EBE-EFPIA Reflection Paper

Conformity with the relevant General Safety Performance Requirements listed in the European Medical Device Regulation 2017/745: Case study for a prefilled pen (prefilled syringe assembled with autoinjector parts forming a single integral product regulated as a medicinal product)

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Final

Executive summary

Article 117 of the Medical Device Regulation (EU) 2017/745 (MDR) requires the Marketing Authorization Applicant to include a Notified Body Opinion on the device constituent, part of a single integral Drug-Device Combination (DDC) in the Marketing Authorization Application, from 26 May 2020. With that, the applicant must demonstrate conformity with the relevant General Safety and Performance Requirements (GSPRs) as outlined in MDR's Annex I.

In the absence of any guidance document on the dossier format and content for fulfillment of the GSPRs especially for single integral drug-device combinations, the EBE DDC topic group has developed the following case study to provide industry's position on how to prove the fulfillment of the GSPRs.

In particular, the case study assesses the target product of a drug prefilled pen which is composed of an auto-injector and a drug prefilled syringe and gives an example of a GSPR checklist.

Each GSPR was assessed for applicability to the defined single integral drug-device combination, applicable method of conformity as well as how industry anticipates demonstrating evidence of conformity with the given GSPR. Special attention was given to the fact that certain GSPRs are superseded by medicinal product requirements that are governing the DDC. Another subset was excluded based on the given technology of the target product or considered only partially applicable where justified. Recent positions published by EBE and EFPIA to overall topics such as labeling or clinical requirements were considered and incorporated. Furthermore, acknowledging different approaches and styles are used across companies, the case study and used terms were developed in a generic manner to allow flexibility but to serve for a general understanding.

Main challenges as well as considerations expressed during the development of the case study are highlighted in the preamble section and should open up further discussion as needed.

With the publishing of that Industry case study, there is a strong desire to increase the exchange on that topic, clarify outstanding questions as well as to give the relevant stakeholders the opportunity in commenting on industry's position.

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List of abbreviations and definitions

AE	Adverse Event
AI	Auto-injector
ASTM	American Society for Testing and Materials
CCS	Container Closure System
CMR/ED	Carcinogenic, Mutagenic or Toxic to Reproduction / Endocrine-Disrupting
DDC	Drug-Device Combination product
EBE	European Biopharmaceutical Enterprises
EC	European Commission
EMA	European Medicines Agency
EU	European Union
GMP	Good Manufacturing Practice
GSPRs	General Safety and Performance Requirements
HCP	Healthcare Provider
ICH	International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
IEC	International Electrotechnical Commission
IFU	Instructions for Use
ISO	International Standard Organization
MDD	Medical Device Directive
MDR	Medical Device Regulation
NB	Notified Body
NBOp	Notified Body Opinion
NSP	Needle Stick Protection
PFP	Prefilled pen
PFS	Prefilled syringe
PIL	Patient Information Leaflet
Ph. Eur.	European Pharmacopoeia
ROW	Rest of the World
SCHEER	Scientific Committee on Health, Environmental and Emerging Risks
SmPC	Summary of Product Characteristics
SOP	Standard Operation Procedure
TBD	To be determined

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1. Introduction

The present case study assesses the "General Safety and Performance Requirements" (GSPRs) relevant to a drug prefilled pen (PFP) when used as an integral Drug-Device Combination (DDC) (= final manufactured, labeled and packaged product)

The PFP consists of a drug prefilled syringe (PFS), the drug primary container, assembled within an auto-injector (AI). Pre-defined characteristics for the PFS include a glass barrel assembled with a staked needle and a stopper. The PFP (PFS + AI) is a single-use, single-dose spring-activated injector intended either for sub-cutaneous self-administration of medicinal product by patients in a house setting environment or administered by a Healthcare Provider (HCP)/Caregiver. The PFP considered in this case study is not connected to any other device and the dose cannot be adjusted. The PFP has an integrated Needle Stick Protection (NSP) feature.

The PFP is a single integral product as defined in Article 1(9) of the Medical Device Regulation (EU) 2017/745 (MDR), which is intended exclusively for use in the given combination and which is not reusable. It is regulated as a medicinal product under Directive 2001/83/EC. According to Article 117 of the MDR, the conformity of the device part with relevant general safety and performance requirements set out in Annex I of the MDR should be demonstrated. This case study defines applicable GSPRs for a PFP, related standards and further references as well as documentation used to demonstrate fulfilment of those GSPRs. Considerations of drug related properties, effects and side effects are not in the scope of this study

Table 1 gives further explanation on the terms used throughout the case study.

Tables 2 - 4 list the standards, compendial references and guidelines/regulations which are applied to the PFP device constituent part to meet the GSPRs. The references listed are a proposal to demonstrate compliance with the GSPRs and are neither seen as exhaustive nor mandatory to be applied but should serve as a basic approach considering the fulfillment of general as well as product specific requirements. For the purpose of this case study, no versions of the respective references such as standards are listed, anticipating the use of the latest generally acknowledged ones unless otherwise justified. In particular, it is anticipated that whenever applicable the harmonized version of the respective standard takes precedence to demonstrate conformity. With respect to the standards applied, ISO 16142-1 "Medical devices — Recognized essential principles of safety and performance of medical devices - Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards" provides general approach for the applicability of different standards in respect to the GSPRs.

Table 5 presents the Annex I "General Safety and Performance Requirements" (GSPRs) of the MDR which are applicable for a PFP including the standards and measures applied that form the basis for the assessment. The purpose of this document is to identify the GSPRs listed in Annex I of the Medical Device Regulation (EU) 2017/745 applicable to either the fully assembled PFP, or to the device constituent parts of the PFP (either the AI or the PFS). When a GSPR is applicable to the PFP, it is applicable to the drug-device combination in its final presentation. It is proposed that platform data (if available) from the manufacturer of the device constituent part may serve as input. Industry's position on the platform approach is currently under development and will be outlined in a separate paper.

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Table 5 also provides references to data as evidence for conformance where applicable considering design and development activities were conducted according to internal Design Control and Risk Management SOPs, utilizing the intent of key international standards and guidance such as ISO 13485, ISO 14971 and ICH Q9 Quality Risk Management.

The GSPRs will be the basis of the assessment by the Notified Body (NB). Since the product under assessment is an integral drug-device combination, some applicable GSPRs for the medical device are also required (in full or in part) for the medicinal product by the Medicinal Products Directive (Directive 2001/83/EC). The performed case study aims to outline an industry proposal for meeting the GSPRs in the context of a PFP.

2. Case Study

2.1 Preamble

The case study was developed considering industry's perspective on how to ensure compliance to the GSPRs. The following considerations and conclusions should be kept in mind for a better understanding of the approach taken.

As per Annex II of the MDR, it is expected that the method of conformity applied to demonstrate compliance with the GSPR is a harmonized standard in the first instance. To cover the fact that MDR harmonization procedures are ongoing and might not be completed once the MDR becomes applicable, it should be acknowledged that where applicable either the current Medical Device Directive (MDD) harmonized or the latest standard version is chosen alternatively. In the context of this case study, standard references are given in a generic way, without stating versions and/or year of release, due to the fast-changing environment towards the effectiveness of the MDR.

Moreover, it should be recognized that in some instances pharma industry applies general principles of the standards that demonstrate conformity with the GSPRs but might not necessarily apply the respective reference in its entirety (e.g. ISO 13485). Due to the fact that a single integral DDC, composed of a medical device and a drug product constituent part is regulated as a medicinal product governed by the Medicinal Products Directive 2001/83/EC, requirements related to this legislation such as EU GMP and ICH guidance or any alternative company internal methods might be in some instances equally appropriate to demonstrate compliance with certain GSPRs or even supersede provisions as outlined in Annex I. However, in that case, reference should be made to the alternative guidance applied.
For the purpose of this case study, EU relevant standards are highlighted as a method of conformity. Considering global development of such a DDC, it should be highlighted that international references are equally considered during development and might serve as an alternative reference supporting the compliance to the GSPRs as applicable and justified. For example, with respect to shipping/transport studies, international acknowledged standards such as ASTM and ISTA are applied and recognized as state of the art.

In addition, it should be highlighted that the case study lists only first level standard references that are found to be applicable to a PFP. If those contain further references that find applicability for the given product, it should be clear that those are adequately addressed as needed. Also, approaches taken to address specific GSPRs are a proposal in the context of this case study.

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Where found helpful further rationale is given in the table. However, the outlined proposal should not be regarded as mandatory but plausible to address the requirements for the target product of a PFP. Across industry, other rationales might exist and may justify for alternative approaches.

Another aspect to consider are the "Common Specifications (CS)" that are introduced by Article 9 of the MDR. Defined as "a set of technical and/or clinical requirements, other than a standard, that provides a means of complying with the legal obligations applicable to a device, process or system."[1] CS will be issued by the European Commission (EC) for fields where no harmonized standards exist, or existing standards are deemed insufficient. As of now, there are no relevant CS for the single-integral DDC to be outlined in this case study. Nevertheless, applicants should be aware that compliance to relevant CS is mandatory according to Article 9 of the MDR unless otherwise duly justified.

Generally, it should be acknowledged that several GSPRs were considered to be not applicable due to the fact that those requirements are superseded by medicinal product requirements. With respect to the DDC chosen within the case study, it should be recognized that aspects in scope of the GSPRs regarding the prefilled syringe, which is assembled in the auto-injector, focus on requirements related to safety and functionality of the device constituent parts. Any considerations and documentation related to the primary packaged drug product and consequently the immediate container closure system are understood to be captured by the marketing authorization application underlying the review of EMA/NCA. Moreover, regarding the labelling section of the GSPRs set out in MDR's Annex I, and in alignment with the EBE/EFPIA view[2], labelling requirements of the medicinal products as it concerns the label are considered taking precedence over those of the medical devices for single integral DDCs as defined in second paragraph of MDR's Article 1(9). However, it is acknowledged that the core "Instructions for Use" (IFU) in its current version at the time of the submission to the NB, which is one component of the medicinal product information (Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL)), will be provided to support the compliance of the relevant GSPR where applicable.

Furthermore, the terms used throughout the case study as evidence of conformance are of a generic nature since approaches and naming across companies might differ. However, to provide a common understanding of the scope of those terms, further information was summarized to address relevant aspects that are covered under the chosen expressions (refer to Section 2.1.1 "Terms").

Industry welcomes relevant stakeholders such as Team NB to comment on the below developed case study in order to work towards a common consent and understanding of the fulfillment of MDR's Annex I in the context of a single integral DDC.

1 MDR, Article 2(71), (OJ L 117 p.20, 05. May 2017)
2 EBE-EFPIA Position Paper, An Industry Perspective on Article 117 of the EU Medical Device Regulation: Labelling Requirements for Prefilled, Non-Reusable, Integral Drug-Delivery Device Combination Products, 08 Aug 2019.

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2.1.1 Terms

In the example GSPR checklist, a number of terms are used that relate to 'Evidence of Conformity'. These terms are defined and explained in Table 1 below.

Table 1 - Explanation of Terms

Term	Definition	Outline of Contents
Risk Management Summary	Summary of risk management activities and outcome for the prefilled pen	Description of the approach taken to risk management including the specific risk management activities that have been performed (e.g. hazard identification and assessment, risk assessments). Details of the benefit/risk analysis and conclusion, plus any ongoing risk management activities. Extracts from detailed documents (e.g. risk assessments) may be included, however the detailed documents themselves will not be included.
Design Verification Summary	Summary of design verification activities and outcome for the prefilled pen	Description of the approach taken to design verification including summaries of the specific design verification activities that have been performed (e.g. Sharps Injury Protection Study Summary, Transport Validation Summary). Extracts from detailed documents (e.g. stability test reports) may be included, however the detailed documents themselves will not be included. Stability/Shelf life test reports are considered to include limited data available at the time of submission to the NB.
Design Validation Summary	Summary of design validation activities and outcome for the prefilled pen	Description of the approach taken to design validation including summaries of the specific design validation activities that have been performed. Extracts from detailed documents may be included, however the detailed documents themselves will not be included.
Clinical Evaluation Summary	Since prefilled pens are regulated as medicinal products, the medicinal	For a prefilled pen, the clinical information required for Notified Body review would typically be incorporated into product

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Term	Definition	Outline of Contents

	products requirements take precedence over medical device requirements.
	
	Consequently, a separate device clinical evaluation/investigation as per Chapter VI "Clinical evaluation and clinical investigations" of the MDR is not required for prefilled pens. However, it is acknowledged that a level of clinical information will need to be submitted to support the Notified Body assessment process.
		development and design control requirements, and as such can be used as supporting evidence to obtain a Notified Body Opinion (NBOp):
		
		• *Scientific literature on the device or equivalent device (precedented use applies)*
		  ○ Peer reviewed publications
		  ○ MAUDE database
		• *Market data*
		  ○ Adverse event (AE) data, customer complaints, recalls, number of sales in EU and ROW, to ensure that data is considered in maintaining patient safety
		  ○ Statistics to compare volume of sales versus device complaint/AE /recalls
		• *Medicinal Product Clinical Trial study/data*
		  Leverage medicinal product clinical trial data involving device
		
		This position is alignment with the EBE/EFPIA paper on this subject: *https://www.ebe-biopharma.eu/publication/ebe-efpia-position-paper-an-industry-perspective-on-article-117-of-the-eu-medical-device-regulation-clinical-requirements-for-prefilled-single-use-integral-drug-device-combination-products/*

Biocompatibility Summary	Summary of biocompatibility activities and outcome the prefilled pen	Description of the approach to taken to establish biocompatibility including summaries of the specific biocompatibility activities that have been performed. Extracts from detailed documents may be included, however the detailed documents themselves will not be included.
Human Factors/	Summary of human factors/	Description of the approach taken to

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Term	Definition	Outline of Contents
Usability Engineering Summary	usability activities and outcome for the prefilled pen	evaluate and establish the usability of the prefilled pen, including summaries of the specific human factors/usability activities that have been performed. Extracts from detailed documents may be included, however the detailed documents themselves will not be included
Instructions for Use (IFU)	The IFU for the prefilled pen is part of the user interface and is subject to Human Factors engineering if relevant for the easy and safe handling of the DDC.	The version of the core IFU that is current at the time of submission to the Notified Body. This version may not be the final version as the IFU is subject to change by the Competent Authority as part of the medicinal product regulatory review and approval process. As applicable, further training documents relevant to the PFP, e.g. Quick Steps Guide, are considered to be provided together with the IFU.
Material Compliance Statements / Certificates	Documents that establish the materials of construction of the prefilled pen comply with the relevant regulatory requirements (e.g. Ph Eur).	Description of the approach taken to establish the materials of the prefilled pen comply with relevant regulatory requirements. Relevant certificates might be included as part of the documentation submitted to the Notified Body for review.

2.1.2 Applied standards, Pharmacopoeias & further Guidance

The PFP has been designed to be in conformance with the applicable sections of the following internationally recognized consensus standards, legislations and guidelines outlined in Tables 2-4 below.

Table 2 - Applied Standards

Standard	Title of Standard
ISO 16142-1	Medical devices — Recognized essential principles of safety and performance of medical devices - Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards
ISO 14971	Medical devices - Application of risk management to medical devices

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Standard	Title of Standard
ISO 11608-1	Needle-based injection systems for medical use - Requirements and test methods - Part 1: Needle-based injection systems
ISO 11608-3	Needle-based injection systems for medical use - Requirements and test methods - Part 3: Finished containers
ISO 11608-5	Needle-based injection systems for medical use - Requirements and test methods - Part 5: Automated functions
ISO 11608-7	Needle-based injection systems for medical use - Requirements and test methods - Part 7: Accessibility for persons with visual impairment
ISO 11040-4	Prefilled syringes – Part 4: Glass barrels for injectables
ISO 11040-5	Prefilled syringes – Part 5: Plunger stoppers for injectables
ISO 11040-8	Prefilled syringes – Part 8: Requirements and test methods for finished prefilled syringes
ISO 9626	Stainless steel needle tubing for the manufacture of medical devices
ISO 23908	Sharps injury protection – Requirements and test methods – Sharps protection features for single-use hypodermic needles, introducers for catheters, and needles used for blood sampling
ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system
IEC 62366-1	Medical devices - Part 1: Application of usability engineering to medical devices
ASTM F1980-16	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ASTM D4169-16[3]	Standard Practice for Performance Testing of Shipping Containers and Systems
ISTA 3E[4]	Similar Packaged Products in Unitized Loads for Truckload Shipment

Table 3 - Applied Pharmacopoeias

Pharmacopoeia	Chapter	Chapter Title
Ph. Eur.	2.9.17.	Test for Extractable Volume of Parenteral Preparations (Section Prefilled Syringes)
Ph. Eur.	2.9.19.	Particulate Contamination: Sub-visible Particles
Ph. Eur.	2.9.20.	Particulate Contamination: Visible Particles
Ph. Eur.	3.2.1	Glass containers for pharmaceutical use

3 depending on final target product other standards might be alternatively applicable where justified
4 depending on final target product other standards might be alternatively applicable where justified

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Pharmacopoeia	Chapter	Chapter Title
Ph. Eur.	3.2.9	Rubber closures for containers for aqueous parenteral preparations, for powders and for freeze-dried powders
Ph. Eur.	3.1.8	Silicone used as a Lubricant
Ph. Eur.	Monograph	Dimeticone

Table 4 - Applied Guidelines & Legislation

Reference Number	Title
Directive 2001/83/EC	Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67–128, as amended)
ICH Q1A	Stability Testing of New Drug Substances and Products Q1A(R2)
ICH Q5C	Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products Q5C
ICH Q9	Quality Risk Management Q9
Regulation (EC) No 1272/2008	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1)
Regulation (EU) No 528/2012	Regulation (EU) No 528/2012 of the European Parliament and the Council of 22 May 2012 concerning the making available on the market of and use of biocidal products (OJ L 167, 27.6.2012, p. 1)
Regulation (EC) No 1907/2006	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 396, 30.12.2006, p. 1).
Regulation (EU) No 722/2012	Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin (OJ L 212, 9.8.2012, p. 3)
EMA/410/01 rev.3	Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMA/410/01 rev.3) (2011/C 73/01)

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Reference Number	Title
SCHEER Guideline on Phthalates	SCHEER (Scientific Committee on Health, Environmental and Emerging Risks), Guidelines on the benefit-risk assessment of the presence of phthalates in certain medical devices covering phthalates which are carcinogenic, mutagenic, toxic to reproduction (CMR) or have endocrine-disrupting (ED) properties, final version adopted at SCHEER plenary on 18 June 2019.

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2.2. ANNEX I - GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

Table 5 – Conformity to the General Safety and Performance Requirements according to Annex I of the MDR 2017/745

	General Safety and Performance Requirements of the Medical Devices Regulation 2017/745	Applicable (Yes or No)	Justification (if needed)	Method of Conformity (Standard / Regulation / Pharmacopoeias)	Evidence of Conformance
Chapter I	**GENERAL REQUIREMENTS**				
1	Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.	Yes	-	ISO 14971 / ICH Q9 IEC 62366-1 ISO 10993 -1	Risk Management Summary Design verification & validation Summary Clinical Evaluation Summary Biocompatibility Summary
2	The requirement in this Annex to reduce risks as far as possible means the reduction of risks as far as possible without adversely affecting the benefit-risk ratio.	Yes	-	ISO 14971 / ICH Q9	Risk Management Summary

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	General Safety and Performance Requirements of the Medical Devices Regulation 2017/745	Applicable (Yes or No)	Justification (if needed)	Method of Conformity (Standard / Regulation / Pharmacopoeias)	Evidence of Conformance
3	Manufacturers shall establish, implement, document and maintain a risk management system. Risk management shall be understood as a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic updating. In carrying out risk management manufacturers shall:				
3 cont.	(a) establish and document a risk management plan for each device.	Yes	-	ISO 14971 / ICH Q9	Risk Management Summary
3 cont.	(b) identify and analyse the known and foreseeable hazards associated with each device.	Yes	-	ISO 14971 / ICH Q9	Risk Management Summary
3 cont.	(c) estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse.	Yes	-	ISO 14971 / ICH Q9	Risk Management Summary
3 cont.	(d) eliminate or control the risks referred to in point (c) in accordance with the requirements of Section 4.	Yes	-	ISO 14971 / ICH Q9	Risk Management Summary



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	General Safety and Performance Requirements of the Medical Devices Regulation 2017/745	Applicable (Yes or No)	Justification (if needed)	Method of Conformity (Standard / Regulation / Pharmacopoeias)	Evidence of Conformance
3 cont.	(e) evaluate the impact of information from the production phase and, in particular, from the post-market surveillance system, on hazards and the frequency of occurrence thereof, on estimates of their associated risks, as well as on the overall risk, benefit-risk ratio and risk acceptability.	Yes	**Partially relevant** Output from Pharmacovigilance information relevant to the device constituent part of the DDC should be considered.	ISO 14971 / ICH Q9	Risk Management Summary
3 cont.	(f) based on the evaluation of the impact of the information referred to in point (e), if necessary amend control measures in line with the requirements of Section 4.	Yes	**Partially relevant** Output from Pharmacovigilance information relevant to the device constituent part of the DDC should be considered.	ISO 14971 / ICH Q9	Risk Management Summary

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	General Safety and Performance Requirements of the Medical Devices Regulation 2017/745	Applicable (Yes or No)	Justification (if needed)	Method of Conformity (Standard / Regulation / Pharmacopoeias)	Evidence of Conformance
4	Risk control measures adopted by manufacturers for the design and manufacture of the devices shall conform to safety principles, taking account of the generally acknowledged state of the art. To reduce risks, Manufacturers shall manage risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable. In selecting the most appropriate solutions, manufacturers shall, in the following order of priority.				
4 cont.	(a) eliminate or reduce risks as far as possible through safe design and manufacture.	Yes	-	ISO 14971 / ICH Q9 ISO 23908 ISO 11608-1 ISO 11608-3 ISO 11608-5 ISO 11608-7 ISO 11040-8 ISO 11040-5 (if applicable) ISO 11040-4 IEC 62366-1	Risk Management Summary Design Validation Summary Design Verification Summary Human Factor/Usability Engineering Summary

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	General Safety and Performance Requirements of the Medical Devices Regulation 2017/745	Applicable (Yes or No)	Justification (if needed)	Method of Conformity (Standard / Regulation / Pharmacopoeias)	Evidence of Conformance
4 cont.	(b) where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated.	Yes	-	ISO 23908 ISO 14971 / ICH Q9	Risk Management Summary Design Verification Summary Design Validation Summary IFU
4 cont.	(c) provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users. Manufacturers shall inform users of any residual risks.	Yes	-	ISO 14971 / ICH Q9 IEC 62366-1	Risk Management Summary Human Factor/Usability Engineering Summary IFU
5	In eliminating or reducing risks related to use error, the manufacturer shall:				

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	General Safety and Performance Requirements of the Medical Devices Regulation 2017/745	Applicable (Yes or No)	Justification (if needed)	Method of Conformity (Standard / Regulation / Pharmacopoeias)	Evidence of Conformance
5 cont.	(a) reduce as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety).	Yes	-	ISO 14971 / ICH Q9 ISO 11608-7 IEC 62366-1	Risk Management Summary Design Verification Summary Design Validation Summary Human Factor/Usability Engineering Summary
5 cont.	(b) give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).	Yes	-	IEC 62366-1 ISO 11608-7	Human Factor/Usability Engineering Summary Design Validation Summary IFU
6	The characteristics and performance of a device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.	Yes	-	ICH Q5C/ICH Q1A ISO 11608-1 ISO 11608-3 ISO 11608-5 ISO 11040-8	Design Verification Summary

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	General Safety and Performance Requirements of the Medical Devices Regulation 2017/745	Applicable (Yes or No)	Justification (if needed)	Method of Conformity (Standard / Regulation / Pharmacopoeias)	Evidence of Conformance
7	Devices shall be designed, manufactured and packaged in such a way that their characteristics and performance during their intended use are not adversely affected during transport and storage, for example, through fluctuations of temperature and humidity, taking account of the instructions and information provided by the manufacturer.	Yes	-	ASTM D4169-16 / ISTA 3E ISO 11608-1 ISO 11608-3 ISO 11608-5 ISO 14971 / ICH Q9	Design Verification Summary Risk Management Summary IFU
8	All known and foreseeable risks, and any undesirable side-effects, shall be minimised and be acceptable when weighed against the evaluated benefits to the patient and/or user arising from the achieved performance of the device during normal conditions of use.	Yes	-	ISO 14971 / ICH Q9	Risk Management Summary Clinical Evaluation Summary
9	For the devices referred to in Annex XVI, the general safety requirements set out in Sections 1 and 8 shall be understood to mean that the device, when used under the conditions and for the purposes intended, does not present a risk at all or presents a risk that is no more than the maximum acceptable risk related to the product's use which is consistent with a high level of protection for the safety and health of persons.	No	**Not relevant based on technology.** The reference applies to device without medical purpose. PFP has medical purpose.	Not applicable	Not applicable

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	General Safety and Performance Requirements of the Medical Devices Regulation 2017/745	Applicable (Yes or No)	Justification (if needed)	Method of Conformity (Standard / Regulation / Pharmacopoeias)	Evidence of Conformance
Chapter II	**REQUIREMENTS REGARDING DESIGN AND MANUFACTURE**				
10	**Chemical, physical and biological properties**				
10.1	Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance requirements referred to in Chapter I are fulfilled. Particular attention shall be paid to:				
10.1 cont.	(a) the choice of materials and substances used, particularly as regards toxicity and, where relevant, flammability.	Yes	-	ISO 10993-1 ISO 11040-4 ISO 11040-5 (if applicable) ISO 9626 Ph. Eur. 3.2.1. Ph.Eur. 3.2.9. Ph. Eur. 3.1.8. / Ph. Eur. Monograph Dimeticone (if applicable)	Design Verification Summary Biocompatibility Summary Certificates of Material Compliance

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10.1 cont.	(b) the compatibility between the materials and substances used and biological tissues, cells and body fluids, taking account of the intended purpose of the device and, where relevant, absorption, distribution, metabolism and excretion.	Yes	-	ISO 10993-1 ISO 9626 ISO 11040-4 ISO 11040-5 (if applicable) Ph. Eur. 3.2.1. Ph.Eur. 3.2.9. Ph. Eur. 3.1.8. / Ph. Eur. Monograph Dimeticone (if applicable)	Biocompatibility Summary Design Verification Summary
10.1 cont.	(c) the compatibility between the different parts of a device which consists of more than one implantable part.	No	**Not relevant based on technology.** The PFP is not implantable	Not applicable	Not applicable
10.1 cont.	(d) the impact of processes on material properties.	Yes	-	ISO 10993-1 ISO 14971 / ICH Q9	Biocompatibility Summary Risk Management Summary

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10.1 cont.	(e) where appropriate, the results of biophysical or modelling research the validity of which has been demonstrated beforehand.	No	**Not relevant based on technology.** The PFP is short term skin contact and short injection duration	Not applicable	Not applicable
10.1 cont.	(f) the mechanical properties of the materials used, reflecting, where appropriate, matters such as strength, ductility, fracture resistance, wear resistance and fatigue resistance.	Yes	-	ASTM F1980-16 ISO 9626 ISO 11040-4 Ph. Eur. 3.2.1. ISO 11608-1 ISO 11608-5 Ph. Eur. 3.1.8. / Ph. Eur. Monograph Dimeticone (if applicable)	Design Verification Summary

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	General Safety and Performance Requirements of the Medical Devices Regulation 2017/745	Applicable (Yes or No)	Justification (if needed)	Method of Conformity (Standard / Regulation / Pharmacopoeias)	Evidence of Conformance
10.1 cont.	(g) surface properties.	Yes	-	Ph. Eur. 3.2.1. Ph.Eur. 3.2.9. Ph. Eur. 3.1.8. / Ph. Eur. Monograph Dimeticone (if applicable)	Design Verification Summary
10.1 cont.	(h) the confirmation that the device meets any defined chemical and/or physical specifications.	Yes	-	ISO 11040-4 Ph.Eur. 3.2.1. Ph. Eur. 3.2.9.	Design Verification Summary
10.2	Devices shall be designed, manufactured and packaged in such a way as to minimise the risk posed by contaminants and residues to patients, taking account of the intended purpose of the device, and to the persons involved in the transport, storage and use of the devices. Particular attention shall be paid to tissues exposed to those contaminants and residues and to the duration and frequency of exposure.	Yes	-	ISO 14791/ICH Q9 ISO 10993-1	Risk Management Summary Design Verification Summary Design Validation Summary Biocompatibility Summary

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10.3	Devices shall be designed and manufactured in such a way that they can be used safely with the materials and substances, including gases, with which they enter into contact during their intended use; if the devices are intended to administer medicinal products they shall be designed and manufactured in such a way as to be compatible with the medicinal products concerned in accordance with the provisions and restrictions governing those medicinal products and that the performance of both the medicinal products and of the devices is maintained in accordance with their respective indications and intended use.	Yes	-	ISO 14791 / ICH Q9 ISO 10993-1 ISO 11608-1 ISO 11608-3 ISO 11608-5 ISO 11040-4 ISO 11040-5 (if applicable) ISO 11040-8 ISO 9626 Ph. Eur. 3.2.1. Ph.Eur. 3.2.9. Ph. Eur. 3.1.8. / Ph. Eur. Monograph Dimeticone (if applicable)	Risk Management Summary Design Verification Summary Design Validation Summary Biocompatibility Summary

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	General Safety and Performance Requirements of the Medical Devices Regulation 2017/745	Applicable (Yes or No)	Justification (if needed)	Method of Conformity (Standard / Regulation / Pharmacopoeias)	Evidence of Conformance
10.4	**Substances**				
10.4.1	Design and manufacture of devices Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by substances or particles, including wear debris, degradation products and processing residues, that may be released from the device. Devices, or those parts thereof or those materials used therein that: • are invasive and come into direct contact with the human body, • (re)administer medicines, body liquids or other substances, including gases, to/from the body, or • transport or Hazardous store such medicines, body fluids or substances, including gases, to be (re)administered to the body, shall only contain the following substances in a concentration that is above 0,1 % weight by weight (w/w) where justified pursuant to Section 10.4.2:	Yes	PFP is in scope of the first paragraph. Second paragraph refers to requirements that are only evaluated for parts that are invasive and come into direct contact with the human body or administer medicinal product. Therefore, the relevant PFS components are assessed only.	ISO 10993-1 ISO 14971 / ICH Q9	Biocompatibility Summary Risk Management Summary

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10.4.1 cont.	(a) substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR'), of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council[5], or	Yes	see justification in 10.4.1 general section	Part 3 of Annex VI to Regulation (EC) No 1272/2008	Material Compliance Statement
10.4.1 cont.	(b) substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified either in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council[6] or, once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article 5(3) of Regulation (EU) No 528/2012 of the European Parliament and the Council[7], in accordance with the criteria that are relevant to human health amongst the criteria established therein.	Yes	see justification in 10.4.1 general section	Article 59 of Regulation (EC) No 1907/2006 or First Paragraph of Article 5(3) of Regulation (EU) No 528/2012 (delegated act)	Material Compliance Statement

5 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1)
6 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 396, 30.12.2006, p. 1).
7 Regulation (EU) No 528/2012 of the European Parliament and the Council of 22 May 2012 concerning the making available on the market of and use of biocidal products (OJ L 167, 27.6.2012, p. 1)

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10.4.2	Justification regarding the presence of CMR and/or endocrine-disrupting substances The justification for the presence of such substances shall be based upon:	Yes	see justification in 10.4.1 general section	Part 3 of Annex VI to Regulation (EC) No 1272/2008 Article 59 of Regulation (EC) No 1907/2006 or First Paragraph of Article 5(3) of Regulation (EU) No 528/2012 (delegated act)	Justification (if applicable)
10.4.2 cont.	(a) an analysis and estimation of potential patient or user exposure to the substance	Yes	see justification in 10.4.1 general section	ISO 14971 / ICH Q9	Risk Management Summary (if applicable) Biocompatibility Summary (if applicable)
10.4.2 cont.	(b) an analysis of possible alternative substances, materials or designs, including, where available, information about independent research, peer-reviewed studies, scientific opinions from relevant scientific committees and an analysis of the availability of such alternatives	Yes	see justification in 10.4.1 general section	ISO 14971 / ICH Q9	Risk Management Summary (if applicable)

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10.4.2 cont.	(c) argumentation as to why possible substance and/ or material substitutes, if available, or design changes, if feasible, are inappropriate in relation to maintaining the functionality, performance and the benefit-risk ratios of the product; including taking into account if the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials	Yes	see justification in 10.4.1 general section	ISO 14971 / ICH Q9	Risk Management Summary (if applicable)
10.4.2 cont.	(d) where applicable and available, the latest relevant scientific committee guidelines in accordance with Sections 10.4.3. and 10.4.4.	Yes	see justification in 10.4.1 general section	SCHEER Guideline on phthalates	Material Compliance Statement

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10.4.3	Guidelines on phthalates For the purposes of Section 10.4., the Commission shall, as soon as possible and by 26 May 2018, provide the relevant scientific committee with a mandate to prepare guidelines that shall be ready before 26 May 2020. The mandate for the committee shall encompass at least a benefit-risk assessment of the presence of phthalates which belong to either of the groups of substances referred to in points (a) and (b) of Section 10.4.1. The benefit-risk assessment shall take into account the intended purpose and context of the use of the device, as well as any available alternative substances and alternative materials, designs or medical treatments. When deemed appropriate on the basis of the latest scientific evidence, but at least every five years, the guidelines shall be updated.	Yes	see justification in 10.4.1 general section	SCHEER Guideline on phthalates	Material Compliance Statement [8] (if applicable)

8 Conclusion of SCHEER Analysis shows that the benefit/risk of use of the substance for the intended purpose is positive



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	General Safety and Performance Requirements of the Medical Devices Regulation 2017/745	Applicable (Yes or No)	Justification (if needed)	Method of Conformity (Standard / Regulation / Pharmacopoeias)	Evidence of Conformance
10.4.4	Guidelines on other CMR and endocrine-disrupting substances Subsequently, the Commission shall mandate the relevant scientific committee to prepare guidelines as referred to in Section 10.4.3. Also for other substances referred to in points (a) and (b) of Section 10.4.1., where appropriate.	Yes	see justification in 10.4.1 general section	CMR/ED Guideline not yet issued (TBD) (alternatively Guideline on phthalates)	Material Compliance Statement [9] (if applicable)
10.4.5	Labelling Where devices, parts thereof or materials used therein as referred to in Section 10.4.1. contain substances referred to in points (a) or (b) of Section 10.4.1. in a concentration above 0,1 % weight by weight (w/w), the presence of those substances shall be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging, with the list of such substances. If the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials, information on residual risks for those patient groups and, if applicable, on appropriate precautionary measures shall be given in the instructions for use.	Yes	Any warnings (e.g., not for use in children, pregnant- or breast-feeding women) included in final SmPC as applicable	-	IFU (if applicable)

9 Conclusion of SCHEER Analysis (or future CMR/ED guideline) shows that the benefit/risk of use of the substance for the intended purpose is positive

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10.5	Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used.	Yes	Relevant Data on Container Closure Integrity as far as it concerns assembly and packaging of PFP will be provided to outline End-to-End Control Strategy.No further considerations are needed for the user testing regarding unintentional ingress as PFP design ensures that unintentional ingress is unlikely as per intended use.	ISO 11040-8 ISO 11608-1 ISO 14971 / ICH Q9 ASTM D4169-16 / ISTA 3E	Risk Management Summary Design Verification Summary

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10.6	Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks linked to the size and the properties of particles which are or can be released into the patient's or user's body, unless they come into contact with intact skin only. Special attention shall be given to nanomaterials.	Yes	**Partially relevant.** Except for nanoparticles, which are usually not included in PFP	ISO 11040-4 Ph.Eur. 2.9.19 / 2.9.20 ISO 11608-3	Design Verification Summary
11	**Infection and microbial contamination**				
11.1	Devices and their manufacturing processes shall be designed in such a way as to eliminate or to reduce as far as possible the risk of infection to patients, users and, where applicable, other persons. The design shall:				
11.1 cont.	(a) reduce as far as possible and appropriate the risks from unintended cuts and pricks, such as needle stick injuries	Yes	-	ISO 23908 ISO 14971 / ICH Q9	Design Verification Summary Risk Management Summary

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11.1 cont.	(b) allow easy and safe handling	Yes	-	IEC 62366-1 ISO 14971 / ICH Q9	Human Factor/Usability Engineering Summary Risk Management Summary
11.1 cont.	(c) reduce as far as possible any microbial leakage from the device and/or microbial exposure during use	Yes	-	ISO 14971 / ICH Q9	Design Verification Summary Risk Management Summary
11.1 cont.	(d) prevent microbial contamination of the device or its content such as specimens or fluids.	Yes	-	ISO 14791 ISO 11040-8 ISO 11608-1 ASTM D4169-16 / ISTA 3E	Risk Management Summary Design Verification Summary
11.2	Where necessary devices shall be designed to facilitate their safe cleaning, disinfection, and/or re-sterilisation.	No	**Not relevant based on technology.** The PFP is single use and does not require cleaning, disinfection or sterilization	Not applicable	Not applicable

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11.3	Devices labelled as having a specific microbial state shall be designed, manufactured and packaged to ensure that they remain in that state when placed on the market and remain so under the transport and storage conditions specified by the manufacturer.	No	**Not relevant based on technology.** The PFP is not labelled as having a specific microbial state	Not applicable	Not applicable
11.4	Devices delivered in a sterile state shall be designed, manufactured and packaged in accordance with appropriate procedures, to ensure that they are sterile when placed on the market and that, unless the packaging which is intended to maintain their sterile condition is damaged, they remain sterile, under the transport and storage conditions specified by the manufacturer, until that packaging is opened at the point of use. It shall be ensured that the integrity of that packaging is clearly evident to the final user.	No	**Not relevant based on technology.** The PFP is not delivered in a sterile state. Relevant parts of the container closure system integrated in the PFP are under the scope of medicinal product requirements.	Not applicable	Not applicable

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11.5	Devices labelled as sterile shall be processed, manufactured, packaged and, sterilized by means of appropriate, validated methods.	No	**Not relevant based on technology.** The PFP is not labelled as sterile	Not applicable	Not applicable
11.6	Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities.	No	**Not relevant based on technology.** The PFP is not intended to be sterilized	Not applicable	Not applicable
11.7	Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the product and, where the devices are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system shall be suitable taking account of the method of sterilisation indicated by the manufacturer.	Yes	**Partially relevant** Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the product.	ASTM D4169-16 / ISTA 3E ISO 14971 / ICH Q9	Design Verification Summary Risk Management Summary

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	General Safety and Performance Requirements of the Medical Devices Regulation 2017/745	Applicable (Yes or No)	Justification (if needed)	Method of Conformity (Standard / Regulation / Pharmacopoeias)	Evidence of Conformance
11.8	The labelling of the device shall distinguish between identical or similar devices placed on the market in both a sterile and a non-sterile condition additional to the symbol used to indicate that devices are sterile.	No	**Not relevant based on technology** The PFP is not placed on the market in two different states.	Not applicable	Not applicable
12	**Devices incorporating a substance considered to be a medicinal product and devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body**		**Superseded by Medicinal Product Requirements** Not applicable since the PFP incorporates a device part but is regulated as a medicinal product governed under Directive 2001/83/EC.		

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	General Safety and Performance Requirements of the Medical Devices Regulation 2017/745	Applicable (Yes or No)	Justification (if needed)	Method of Conformity (Standard / Regulation / Pharmacopoeias)	Evidence of Conformance
12.1	In the case of devices referred to in the first subparagraph of Article 1(8), the quality, safety and usefulness of the substance which, if used separately, would be considered to be a medicinal product within the meaning of point (2) of Article 1 of Directive 2001/83/EC, shall be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC, as required by the applicable conformity assessment procedure under this Regulation.	No	Not applicable	Not applicable	Not applicable
12.2	Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body, and that are absorbed by or locally dispersed in the human body shall comply, where applicable and in a manner limited to the aspects not covered by this Regulation, with the relevant requirements laid down in Annex I to Directive 2001/83/EC for the evaluation of absorption, distribution, metabolism, excretion, local tolerance, toxicity, interaction with other devices, medicinal products or other substances and potential for adverse reactions, as required by the applicable conformity assessment procedure under this Regulation.	No	Not applicable	Not applicable	Not applicable
13	**Devices incorporating materials of biological origin**				
13.1	For devices manufactured utilising derivatives of tissues or cells of human origin which are non-viable or are rendered non-viable covered by this Regulation in accordance with point (g) of Article 1(6), the following shall apply:	Not applicable	Not applicable	Not applicable	Not applicable

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	General Safety and Performance Requirements of the Medical Devices Regulation 2017/745	Applicable (Yes or No)	Justification (if needed)	Method of Conformity (Standard / Regulation / Pharmacopoeias)	Evidence of Conformance
13.1 cont.	(a) donation, procurement and testing of the tissues and cells shall be done in accordance with Directive 2004/23/EC	Not applicable	Not applicable	Not applicable	Not applicable
13.1 cont.	(b) processing, preservation and any other handling of those tissues and cells or their derivatives shall be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process	Not applicable	Not applicable	Not applicable	Not applicable
13.1 cont.	(c) the traceability system for those devices shall be complementary and compatible with the traceability and data protection requirements laid down in Directive 2004/23/EC and in Directive 2002/98/EC	Not applicable	Not applicable	Not applicable	Not applicable

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	General Safety and Performance Requirements of the Medical Devices Regulation 2017/745	Applicable (Yes or No)	Justification (if needed)	Method of Conformity (Standard / Regulation / Pharmacopoeias)	Evidence of Conformance
13.2	For devices manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable the following shall apply:	Yes	**Requirements for Container Closure System (CCS) are superseded by medicinal product requirements** CCS is assessed against EMA Guidance[10]. As far as the device components with no drug product contact are concerned this is assessed against the indicated references.		

10 Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMA/410/01 rev.3)

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	General Safety and Performance Requirements of the Medical Devices Regulation 2017/745	Applicable (Yes or No)	Justification (if needed)	Method of Conformity (Standard / Regulation / Pharmacopoeias)	Evidence of Conformance
13.2 cont.	(a) where feasible taking into account the animal species, tissues and cells of animal origin, or their derivatives, shall originate from animals that have been subjected to veterinary controls that are adapted to the intended use of the tissues. Information on the geographical origin of the animals shall be retained by manufacturers	Yes	see justification above	EMA/410/01 rev.3 (Container Closure System)	Material Compliance Statement
13.2 cont.	(b) sourcing, processing, preservation, testing and handling of tissues, cells and substances of animal origin, or their derivatives, shall be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process, except when the use of such methods would lead to unacceptable degradation compromising the clinical benefit of the device	Yes	see justification above	EMA/410/01 rev.3 (Container Closure System)	Material Compliance Statement
13.2 cont.	(c) in the case of devices manufactured utilising tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012 the particular requirements laid down in that Regulation shall apply	Yes	see justification above	Regulation (EU) No 722/2012	Material Compliance Statement

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13.3	For devices manufactured utilising non-viable biological substances other than those referred to in Sections 13.1 and 13.2, the processing, preservation, testing and handling of those substances shall be carried out so as to provide safety for patients, users and, where applicable, other persons, including in the waste disposal chain. In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.	Not applicable	Not applicable	Not applicable	Not applicable
14	**Construction of devices and interaction with their environment**				
14.1	If the device is intended for use in combination with other devices or equipment the whole combination, including the connection system shall be safe and shall not impair the specified performance of the devices. Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use. Connections which the user has to handle, such as fluid, gas transfer, electrical or mechanical coupling, shall be designed and constructed in such a way as to minimise all possible risks, such as misconnection.	No	**Not relevant based on technology** Not applicable since the PFP is not intended for use in combination with other devices, unless the PFP has connectivity features	Not applicable	Not applicable
14.2	Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible:				



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14.2 cont.	(a) the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features	Yes	-	ISO 23908 IEC 62366-1 ISO 14971 / ICH Q9	Human Factor/Usability Engineering Summary Design Verification Summary Risk Management Summary
14.2 cont.	(b) risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences	Yes	**Partially relevant** Defined PFP is not externally influenced by magnetic fields, electrical and electromagnetic effects, electrostatic discharge, radiation or radio signal interferences.	ASTM D4169-16 / ISTA 3E ISO 14971 / ICH Q9 IEC 62366-1 ISO 11608-1 ICH Q5C/Q1A	Risk Management Summary Human Factor/Usability Engineering Summary Design Verification Summary

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14.2 cont.	c) the risks associated with the use of the device when it comes into contact with materials, liquids, and substances, including gases, to which it is exposed during normal conditions of use	Yes	-	ISO 14971 / ICH Q9	Risk Management Summary
14.2 cont.	(d) the risks associated with the possible negative interaction between software and the IT environment within which it operates and interacts	No	**Not relevant based on technology** Provided the PFP does not contain software.	Not applicable	Not applicable
14.2 cont.	(e) the risks of accidental ingress of substances into the device	Yes	-	ISO 11040-4 ISO 14971 / ICH Q9 ASTM D4169-16 / ISTA 3E	Risk Management Summary Design Verification Summary
14.2 cont.	(f) the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given.	No	**Not relevant based on technology** Provided that the PFP is spring-operated and does not include any electronics	Not applicable	Not applicable

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14.2 cont.	(g) risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.	Yes	-	ISO 14971 / ICH Q9 ICH Q5C/Q1A ISO 11608-1 ISO 11608-3 ISO 11608-5 ISO 11040-8 Ph. Eur. 2.9.17.	Design Verification Summary
14.3	Devices shall be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition. Particular attention shall be paid to devices the intended use of which includes exposure to or use in association with flammable or explosive substances or substances which could cause combustion.	No	**Not relevant based on technology** PFP usually present no risk of explosion	Not applicable	Not applicable
14.4	Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively.	No	**Not relevant based on technology** PFP are single use and do not require adjustment, calibration, and maintenance	Not applicable	Not applicable

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	General Safety and Performance Requirements of the Medical Devices Regulation 2017/745	Applicable (Yes or No)	Justification (if needed)	Method of Conformity (Standard / Regulation / Pharmacopoeias)	Evidence of Conformance
14.5	Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe.	No	**Not relevant based on technology** PFP is considered a single integral DDC.	Not applicable	Not applicable
14.6	Any measurement, monitoring or display scale shall be designed and manufactured in line with ergonomic principles, taking account of the intended purpose, users and the environmental conditions in which the devices are intended to be used.	Yes	**Partially relevant** Typically, no measurement or display scale.	IEC 62366-1 ISO 11608-1 ISO 11608-3	Design Verification Summary Human Factor/Usability Engineering Summary
14.7	Devices shall be designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of related waste substances by the user, patient or other person. To that end, manufacturers shall identify and test procedures and measures as a result of which their devices can be safely disposed after use. Such procedures shall be described in the instructions for use.	Yes	Defined PFP has an integrated Needle Stick Protection supporting safe disposal requirements.	ISO 14971 / ICH Q9 ISO 23908 IEC 62366-1	Risk Management Summary IFU Human Factor/Usability Engineering Summary
15	**Devices with a diagnostic or measuring function**				
15.1	Diagnostic devices and devices with a measuring function, shall be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose, based on appropriate scientific and technical methods. The limits of accuracy shall be indicated by the manufacturer.	No	**Not relevant based on technology** PFP do not have a diagnostic or measuring function	Not applicable	Not applicable

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15.2	The measurements made by devices with a measuring function shall be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC[11]	No	**Not relevant based on technology** PFP do not have a diagnostic or measuring function	Not applicable	Not applicable
16	**Protection against radiation**		**Not relevant based on technology** PFP do not emit radiation		
16.1	*General*				
16.1 cont.	(a) Devices shall be designed, manufactured and packaged in such a way that exposure of patients, users and other persons to radiation is reduced as far as possible, and in a manner that is compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.	No	Not applicable	Not applicable	Not applicable

11 Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement and on the repeal of Directive 71/354/EEC (OJ L 39, 15.2.1980, p. 40).

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	General Safety and Performance Requirements of the Medical Devices Regulation 2017/745	Applicable (Yes or No)	Justification (if needed)	Method of Conformity (Standard / Regulation / Pharmacopoeias)	Evidence of Conformance
16.1 cont.	(b) The operating instructions for devices emitting hazardous or potentially hazardous radiation shall contain detailed information as to the nature of the emitted radiation, the means of protecting the patient and the user, and on ways of avoiding misuse and of reducing the risks inherent to installation as far as possible and appropriate. Information regarding the acceptance and performance testing, the acceptance criteria, and the maintenance procedure shall also be specified.	No	Not applicable	Not applicable	Not applicable
16.2	*Intended radiation*				
16.2 cont.	(a) Where devices are designed to emit hazardous, or potentially hazardous, levels of ionizing and/or non- ionizing radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent to the emission, it shall be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance.	No	Not applicable	Not applicable	Not applicable
16.2 cont.	(b) Where devices are intended to emit hazardous, or potentially hazardous, ionizing and/or non-ionizing radiation, they shall be fitted, where possible, with visual displays and/or audible warnings of such emissions.	No	Not applicable	Not applicable	Not applicable

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16.3	Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible. Where possible and appropriate, methods shall be selected which reduce the exposure to radiation of patients, users and other persons who may be affected.	No	Not applicable	Not applicable	Not applicable
16.4	*Ionising radiation*				
16.4 cont.	(a) Devices intended to emit ionizing radiation shall be designed and manufactured taking into account the requirements of the Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation.	No	Not applicable	Not applicable	Not applicable
16.4 cont.	(b) Devices intended to emit ionising radiation shall be designed and manufactured in such a way as to ensure that, where possible, taking into account the intended use, the quantity, geometry and quality of the radiation emitted can be varied and controlled, and, if possible, monitored during treatment.	No	Not applicable	Not applicable	Not applicable
16.4 cont.	(c) Devices emitting ionising radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve an image and/or output quality that are appropriate to the intended medical purpose whilst minimising radiation exposure of the patient and user.	No	Not applicable	Not applicable	Not applicable

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16.4 cont.	(d) Devices that emit ionising radiation and are intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type, energy and, where appropriate, the quality of radiation.	No	Not applicable	Not applicable	Not applicable
17	**Electronic programmable systems — devices that incorporate electronic programmable systems and software that are devices in themselves**		**Not relevant based on technology** Not applicable: the PFP does not enter the definition		
17.1	Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, shall be designed to ensure repeatability, reliability and performance in line with their intended use. In the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks or impairment of performance.	No	Not applicable	Not applicable	Not applicable
17.2	For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation.	No	Not applicable	Not applicable	Not applicable

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17.3	Software referred to in this Section that is intended to be used in combination with mobile computing platforms shall be designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards level of light or noise).	No	Not applicable	Not applicable	Not applicable
17.4	Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.	No	Not applicable	Not applicable	Not applicable
18	**Active devices and devices connected to them**		Defined PFP is an active device, which is spring-operated, but it is typically not connected to another device (e.g. power supply)		
18.1	For non-implantable active devices, in the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks.	Yes	-	ISO 14971 / ICH Q9	IFU Risk Management Summary

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18.2	Devices where the safety of the patient depends on an internal power supply shall be equipped with a means of determining the state of the power supply and an appropriate warning or indication for when the capacity of the power supply becomes critical. If necessary, such warning or indication shall be given prior to the power supply becoming critical.	No	**Not relevant based on technology** No electric power supply	Not applicable	Not applicable
18.3	Devices where the safety of the patient depends on an external power supply shall include an alarm system to signal any power failure.	No	**Not relevant based on technology** No external power supply	Not applicable	Not applicable
18.4	Devices intended to monitor one or more clinical parameters of a patient shall be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.	No	**Not relevant based on technology** PFP is not intended to monitor clinical parameters	Not applicable	Not applicable
18.5	Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks of creating electromagnetic interference which could impair the operation of the device in question or other devices or equipment in the intended environment.	No	**Not relevant based on technology** No electronic features	Not applicable	Not applicable

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18.6	Devices shall be designed and manufactured in such a way as to provide a level of intrinsic immunity to electromagnetic interference such that is adequate to enable them to operate as intended.	No	**Not relevant based on technology** No electronic features	Not applicable	Not applicable
18.7	Devices shall be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks to the patient, user or any other person, both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed and maintained as indicated by the manufacturer.	No	**Not relevant based on technology** No electronic features	Not applicable	Not applicable

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18.8	Devices shall be designed and manufactured in such a way as to protect, as far as possible, against unauthorised access that could hamper the device from functioning as intended.	No	**Superseded by medicinal product requirements** Requirements are covered by compliance with the Falsified Medicines Directive 2011/62/EU[12] and design of secondary packaging of medicinal product.	Not applicable	Not applicable
19	**Particular requirements for active implantable devices**		**Not relevant based on technology** The PFP does not enter the definition of implantable device		

12 DIRECTIVE 2011/62/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products (OJ L 174 p.74-87, 01. July 2011).

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19.1	Active implantable devices shall be designed and manufactured in such a way as to remove or minimize as far as possible:	No	Not applicable	Not applicable	Not applicable
19.1 cont.	(a) risks connected with the use of energy sources with particular reference, where electricity is used, to insulation, leakage currents and overheating of the devices	No	Not applicable	Not applicable	Not applicable
19.1 cont.	(b) risks connected with medical treatment, in particular those resulting from the use of defibrillators or high- frequency surgical equipment, and	No	Not applicable	Not applicable	Not applicable
19.1 cont.	(c) risks which may arise where maintenance and calibration are impossible, including: • excessive increase of leakage currents • ageing of the materials used • excess heat generated by the device • decreased accuracy of any measuring or control mechanism	No	Not applicable	Not applicable	Not applicable
19.2	Active implantable devices shall be designed and manufactured in such a way as to ensure • if applicable, the compatibility of the devices with the substances they are intended to administer • the reliability of the source of energy	No	Not applicable	Not applicable	Not applicable

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19.3	Active implantable devices and, if appropriate, their component parts shall be identifiable to allow any necessary measure to be taken following the discovery of a potential risk in connection with the devices or their component parts.	No	Not applicable	Not applicable	Not applicable
19.4	Active implantable devices shall bear a code by which they and their manufacturer can be unequivocally identified (particularly with regard to the type of device and its year of manufacture); it shall be possible to read this code, if necessary, without the need for a surgical operation.	No	Not applicable	Not applicable	Not applicable
20	**Protection against mechanical and thermal risks**				
20.1	Devices shall be designed and manufactured in such a way as to protect patients and users against mechanical risks connected with, for example, resistance to movement, instability and moving parts.	Yes	-	ISO 14971 / ICH Q9 ISO 23908 ISO 11608-1 ISO 11608-3 ISO 11608-5 ASTM D4169-16 / ISTA 3E	Risk Management Summary Design Verification Summary

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20.2	Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.	No	**Not relevant based on technology** The PFP does not emit vibrations	Not applicable	Not applicable
20.3	Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.	No	**Not relevant based on technology** The PFP does not emit sounds other than intended as per DDC design.	Not applicable	Not applicable
20.4	Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user or other person has to handle, shall be designed and constructed in such a way as to minimise all possible risks.	No	**Not relevant based on technology** The PFP has no connectors to electricity, gas or hydraulic and pneumatic energy supplies.	Not applicable	Not applicable

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20.5	Errors likely to be made when fitting or refitting certain parts which could be a source of risk shall be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings. The same information shall be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk.	Yes	**Partially relevant** No (re-) fitting applicable based on technology.	IEC 62366-1 ISO 14971 / ICH Q9	Human Factor/Usability Engineering Summary IFU Risk Management Summary
20.6	Accessible parts of devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings shall not attain potentially dangerous temperatures under normal conditions of use.	No	**Not relevant based on technology** Not applicable as the PFP does not present thermal risks	Not applicable	Not applicable
21	**Protection against the risks posed to the patient or user by devices supplying energy or substances**		The energy supply comes from the spring, which ensures the deployment of the needle and injection of the drug		

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	General Safety and Performance Requirements of the Medical Devices Regulation 2017/745	Applicable (Yes or No)	Justification (if needed)	Method of Conformity (Standard / Regulation / Pharmacopoeias)	Evidence of Conformance
21.1	Devices for supplying the patient with energy or substances shall be designed and constructed in such a way that the amount to be delivered can be set and maintained accurately enough to ensure the safety of the patient and of the user.	Yes	**Partially relevant** Single-dose PFP	ISO 11608-1 ISO 11608-5 Ph. Eur. 2.9.17. IEC 62366-1	Design Verification Summary Certificate of Analysis Human Factor/Usability Engineering Summary
21.2	Devices shall be fitted with the means of preventing and/or indicating any inadequacies in the amount of energy delivered or substances delivered which could pose a danger. Devices shall incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy or substances from an energy and/or substance source.	Yes	-	ISO 14971 / ICH Q9 IEC 62366-1	Design Verification Summary Risk Management Summary Human Factor/Usability Engineering Summary
21.3	The function of the controls and indicators shall be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information shall be understandable to the user and, as appropriate, the patient.	Yes	-	IEC 62366-1	IFU Human Factor/Usability Engineering Summary
22	**Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons**				

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	General Safety and Performance Requirements of the Medical Devices Regulation 2017/745	Applicable (Yes or No)	Justification (if needed)	Method of Conformity (Standard / Regulation / Pharmacopoeias)	Evidence of Conformance
22.1	Devices for use by lay persons shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to lay persons and the influence resulting from variation that can be reasonably anticipated in the lay person's technique and environment. The information and instructions provided by the manufacturer shall be easy for the lay person to understand and apply.	Yes	-	ISO 14971 / ICH Q9 IEC 62366-1	Risk Management Summary Human Factor/Usability Engineering Summary IFU
22.2	Devices for use by lay persons shall be designed and manufactured in such a way as to: • ensure that the device can be used safely and accurately by the intended user at all stages of the procedure, if necessary after appropriate training and/or information • reduce, as far as possible and appropriate, the risk from unintended cuts and pricks such as needle stick injuries • reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, in the interpretation of the results.	Yes	-	ISO 14971 / ICH Q9 IEC 62366-1 ISO 23908	Design Verification Summary IFU Human Factor/Usability Engineering Summary Risk Management Summary

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	General Safety and Performance Requirements of the Medical Devices Regulation 2017/745	Applicable (Yes or No)	Justification (if needed)	Method of Conformity (Standard / Regulation / Pharmacopoeias)	Evidence of Conformance
22.3	Devices for use by lay persons shall, where appropriate, include a procedure by which the lay person: • can verify that, at the time of use, the device will perform as intended by the manufacturer • if applicable, is warned if the device has failed to provide a valid result.	Yes	-	IEC 62366-1 ISO 14971 / ICH Q9	IFU Human Factor/Usability Engineering Summary Risk Management Summary
Chapter III	**REQUIREMENTS REGARDING THE INFORMATION SUPPLIED WITH THE DEVICE**				
23	**Label and instructions for use**				
23.1	General requirements regarding the information supplied by the manufacturer Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user, or any other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a website, be made available and kept up to date on the website, taking into account the following:	Yes	-	-	-

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	General Safety and Performance Requirements of the Medical Devices Regulation 2017/745	Applicable (Yes or No)	Justification (if needed)	Method of Conformity (Standard / Regulation / Pharmacopoeias)	Evidence of Conformance
23.1 cont.	(a) The medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions for use shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams.	Yes	**Partially relevant** Label requirements are superseded by medicinal product requirements.	IEC 62366-1	IFU Human Factor / Usability engineering Summary
23.1 cont.	(b) The information required on the label shall be provided on the device itself. If this is not practicable or appropriate, some or all of the information may appear on the packaging for each unit, and/or on the packaging of multiple devices.	No	**Superseded by Medicinal Product Requirements** Governed by 2001/83/EC	Not applicable	Not applicable
23.1 cont.	(c) Labels shall be provided in a human-readable format and may be supplemented by machine-readable information, such as radio-frequency identification ('RFID') or bar codes.	No	**Superseded by Medicinal Product Requirements** Governed by 2001/83/EC	´Not applicable	Not applicable

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23.1 cont.	(d) Instructions for use shall be provided together with devices. By way of exception, instructions for use shall not be required for class I and class IIa devices if such devices can be used safely without any such instructions and unless otherwise provided for elsewhere in this Section.	No	**Superseded by Medicinal Product Requirements** Exception does not apply, instructions for use will always have to go into the SmPC/PIL regardless of risk category	Not applicable	Not applicable
23.1 cont.	(e) Where multiple devices are supplied to a single user and/or location, a single copy of the instructions for use may be provided if so agreed by the purchaser who in any case may request further copies to be provided free of charge.	No	**Superseded by Medicinal Product Requirements** Not foreseen by 2001/83/EC	Not applicable	Not applicable
23.1 cont.	f) Instructions for use may be provided to the user in non-paper format (e.g. electronic) to the extent, and only under the conditions, set out in Regulation (EU) No 207/2012 or in any subsequent implementing rules adopted pursuant to this Regulation.	No	**Superseded by Medicinal Product Requirements** Only paper version required by 2001/83/EC	Not applicable	Not applicable

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	General Safety and Performance Requirements of the Medical Devices Regulation 2017/745	Applicable (Yes or No)	Justification (if needed)	Method of Conformity (Standard / Regulation / Pharmacopoeias)	Evidence of Conformance
23.1 cont.	(g) Residual risks which are required to be communicated to the user and/or other person shall be included as limitations, contra-indications, precautions or warnings in the information supplied by the manufacturer.	Yes	**Partially relevant** Governed by 2001/83/EC. Warnings, contra-indications etc, covered in relevant SmPC section. Only to extent device-specific warnings or precautions are included in draft IFU.	-	IFU
23.1 cont.	(h) Where appropriate, the information supplied by the manufacturer shall take the form of internationally recognised symbols. Any symbol or identification colour used shall conform to the harmonised standards or CS. In areas for which no harmonised standards or CS exist, the symbols and colours shall be described in the documentation supplied with the device.	No	**Superseded by Medicinal Product Requirements** Governed by 2001/83/EC	Not applicable	Not applicable

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23.2	Information on the label The label shall bear all of the following particulars:	No	**Superseded by Medicinal Product Requirements** Labelling requirements are governed by 2001/83/EC	Not applicable	Not applicable
23.2 cont.	(a) the name or trade name of the device	No	See justification above	Not applicable	Not applicable
23.2 cont.	(b) the details strictly necessary for a user to identify the device, the contents of the packaging and, where it is not obvious for the user, the intended purpose of the device.	No	See justification above	Not applicable	Not applicable
23.2 cont.	(c) the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business.	No	See justification above	Not applicable	Not applicable
23.2 cont.	(d) if the manufacturer has its registered place of business outside the Union, the name of the authorised representative and address of the registered place of business of the authorised representative.	No	See justification above	Not applicable	Not applicable

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23.2 cont.	(e) where applicable, an indication that the device contains or incorporates: • a medicinal substance, including a human blood or plasma derivative, or • tissues or cells, or their derivatives, of human origin, or • tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012	No	See justification above	Not applicable	Not applicable
23.2 cont.	(f) where applicable, information labelled in accordance with Section 10.4.5	No	See justification above	Not applicable	Not applicable
23.2 cont.	(g) the lot number or the serial number of the device preceded by the words LOT NUMBER or SERIAL NUMBER or an equivalent symbol, as appropriate	No	See justification above	Not applicable	Not applicable
23.2 cont.	(h) the UDI carrier referred to in Article 27(4) and Part C of Annex VII	No	See justification above	Not applicable	Not applicable
23.2 cont.	(i) an unambiguous indication of t the time limit for using or implanting the device safely, expressed at least in terms of year and month, where this is relevant	No	See justification above	Not applicable	Not applicable
23.2 cont.	(j) where there is no indication of the date until when it may be used safely, the date of manufacture. This date of manufacture may be included as part of the lot number or serial number, provided the date is clearly identifiable	No	See justification above	Not applicable	Not applicable



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23.2 cont.	(k) an indication of any special storage and/or handling condition that applies	No	See justification above	Not applicable	Not applicable
23.2 cont.	(l) if the device is supplied sterile, an indication of its sterile state and the sterilisation method	No	See justification above	Not applicable	Not applicable
23.2 cont.	(m) warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device, and to any other person. This information may be kept to a minimum in which case more detailed information shall appear in the instructions for use, taking into account the intended users	No	See justification above	Not applicable	Not applicable
23.2 cont.	(n) if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union	No	See justification above	Not applicable	Not applicable
23.2 cont.	(o) if the device is a single-use device that has been reprocessed, an indication of that fact, the number of reprocessing cycles already performed, and any limitation as regards the number of reprocessing cycles	No	See justification above	Not applicable	Not applicable
23.2 cont.	(p) if the device is custom-made, the words 'custom-made device'	No	See justification above	Not applicable	Not applicable
23.2 cont.	(q) an indication that the device is a medical device. If the device is intended for clinical investigation only, the words 'exclusively for clinical investigation'	No	See justification above	Not applicable	Not applicable

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23.2 cont.	(r) in the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body, the overall qualitative composition of the device and quantitative information on the main constituent or constituents responsible for achieving the principal intended action	No	See justification above	Not applicable	Not applicable
23.2 cont.	(s) for active implantable devices, the serial number, and for other implantable devices, the serial number or the lot number	No	See justification above	Not applicable	Not applicable
23.3	Information on the packaging which maintains the sterile condition of a device ('sterile packaging') The following particulars shall appear on the sterile packaging:	No	**Superseded by Medicinal Product Requirements** Labelling requirements are governed by 2001/83/EC.	Not applicable	Not applicable
23.3 cont.	(a) an indication permitting the sterile packaging to be recognised as such,	No	See justification above	Not applicable	Not applicable
23.3 cont.	(b) a declaration that the device is in a sterile condition	No	See justification above	Not applicable	Not applicable

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23.3 cont.	(c) the method of sterilisation	No	See justification above	Not applicable	Not applicable
23.3 cont.	(d) the name and address of the manufacturer	No	See justification above	Not applicable	Not applicable
23.3 cont.	(e) a description of the device	No	See justification above	Not applicable	Not applicable
23.3 cont.	(f) if the device is intended for clinical investigations, the words 'exclusively for clinical investigations'	No	See justification above	Not applicable	Not applicable
23.3 cont.	(g) if the device is custom-made, the words 'custom-made device'	No	See justification above	Not applicable	Not applicable
23.3 cont.	(h) the month and year of manufacture	No	See justification above	Not applicable	Not applicable
23.3 cont.	(i) an unambiguous indication of the time limit for using or implanting the device safely expressed at least in terms of year and month	No	See justification above	Not applicable	Not applicable
23.3 cont.	(j) an instruction to check the instructions for use for what to do if the sterile packaging is damaged or unintentionally opened before use	No	See justification above	Not applicable	Not applicable
23.4	Information in the instructions for use The instructions for use shall contain all of the following particulars:				

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23.4 cont.	(a) the particulars referred to in points (a), (c), (e), (f), (k), (l), (n) and (r) of Section 23.2	Yes	**Partially relevant** (sub-paragraphs f, k, n) Relevant information applicable to the PFP will be included such as indication of substances according 10.4.5 (if applicable), single use and storage/handling conditions.	– Refer to comments under 10.4.5	– Refer to comments under 10.4.5 IFU
23.4 cont.	(b) the device's intended purpose with a clear specification of indications, contra-indications, the patient target group or groups, and of the intended users, as appropriate	No	**Superseded by Medicinal Product Requirements** Governed by 2001/83/EC	Not applicable	Not applicable

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23.4 cont.	(c) where applicable, a specification of the clinical benefits to be expected	No	**Superseded by Medicinal Product Requirements** Governed by 2001/83/EC	Not applicable	Not applicable
23.4 cont.	(d) where applicable, links to the summary of safety and clinical performance referred to in Article 32	No	**Superseded by Medicinal Product Requirements** Governed by 2001/83/EC	Not applicable	Not applicable
23.4 cont.	(e) the performance characteristics of the device	No	**Superseded by Medicinal Product Requirements** Part of the NB conformance assessment but not the label, which is governed by 2001/83/EC	Not applicable	Not applicable

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23.4 cont.	(f) where applicable, information allowing the healthcare professional to verify if the device is suitable and select the corresponding software and accessories	No	**Superseded by Medicinal Product Requirements** Governed by 2001/83/EC	Not applicable	Not applicable
23.4 cont.	(g) any residual risks, contra-indications and any undesirable side-effects, including information to be conveyed to the patient in this regard	Yes	**Partially relevant** Governed by 2001/83/EC. Warnings, contra-indications etc, covered in relevant SmPC section. Only to extent device-specific warnings or precautions are included in draft IFU	ISO 14971 / ICH Q9 ISO 11608-1	IFU
23.4 cont.	(h) specifications the user requires to use the device appropriately, e.g. if the device has a measuring function, the degree of accuracy claimed for it	Yes	-	ISO 11608-1	IFU

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23.4 cont.	(i) details of any preparatory treatment or handling of the device before it is ready for use or during its use, such as sterilisation, final assembly, calibration, etc., including the levels of disinfection required to ensure patient safety and all available methods for achieving those levels of disinfection	Yes	-	ISO 11608-1	IFU
23.4 cont.	(j) any requirements for special facilities, or special training, or particular qualifications of the device user and/or other persons	Yes	-	-	IFU
23.4 cont.	(k) the information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant: • details of the nature, and frequency, of preventive and regular maintenance, and of any preparatory cleaning or disinfection, • identification of any consumable components and how to replace them, • information on any necessary calibration to ensure that the device operates properly and safely during its intended lifetime, and • methods for eliminating the risks encountered by persons involved in installing, calibrating or servicing devices;	No	**Not relevant based on technology.** As per definition the PFP is integral, non-reusable, not assembled	Not applicable	Not applicable

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23.4 cont.	(l) if the device is supplied sterile, instructions in the event of the sterile packaging being damaged or unintentionally opened before use	No	**Not relevant based on technology.** PFP is not sterilized.	Not applicable	Not applicable
23.4 cont.	(m) if the device is supplied non-sterile with the intention that it is sterilised before use, the appropriate instructions for sterilisation	No	**Not relevant based on technology.** PFP is not sterilized.	Not applicable	Not applicable
23.4 cont.	(n) if the device is reusable, information on the appropriate processes for allowing reuse, including cleaning, disinfection, packaging and, where appropriate, the validated method of re-sterilisation appropriate to the Member State or Member States in which the device has been placed on the market. Information shall be provided to identify when the device should no longer be reused, e.g. signs of material degradation or the maximum number of allowable reuses	No	**Not relevant based on technology.** PFP is not reusable.	Not applicable	Not applicable
23.4 cont.	(o) an indication, if appropriate, that a device can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the general safety and performance requirements	No	**Not relevant based on technology.** PFP is not reusable.	Not applicable	Not applicable

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23.4 cont.	(p) if the device bears an indication that it is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. This information shall be based on a specific section of the manufacturer's risk management documentation, where such characteristics and technical factors shall be addressed in detail. If in accordance with point (d) of Section 23.1. no instructions for use are required, this information shall be made available to the user upon request	No	**Superseded by Medicinal Product Requirements** Governed by 2001/83/EC & SmPC Guidelines	Not applicable	Not applicable
23.4 cont.	(q) for devices intended for use together with other devices and/or general purpose equipment: • information to identify such devices or equipment, in order to obtain a safe combination, and/or • information on any known restrictions to combinations of devices and equipment	No	**Not relevant based on technology.** No other device intended for use together defined.	Not applicable	Not applicable
23.4 cont.	(r) if the device emits radiation for medical purposes: • detailed information as to the nature, type and where appropriate, the intensity and distribution of the emitted radiation, • the means of protecting the patient, user, or other person from unintended radiation during use of the device	No	**Not relevant based on technology.** PFP is not emitting radiation.	Not applicable	Not applicable

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23.4 cont.	(s) information that allows the user and/or patient to be informed of any warnings, precautions, contra- indications, measures to be taken and limitations of use regarding the device. That information shall, where relevant, allow the user to brief the patient about any warnings, precautions, contra-indications, measures to be taken and limitations of use regarding the device. The information shall cover, where appropriate: • warnings, precautions and/or measures to be taken in the event of malfunction of the device or changes in its performance that may affect safety • warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature • warnings, precautions and/or measures to be taken as regards the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, or therapeutic treatment or other procedures such as electromagnetic interference emitted by the device affecting other equipment • if the device is intended to administer medicinal products, tissues or cells of human or animal origin, or their derivatives, or biological substances, any limitations or incompatibility in the choice of substances to be delivered • if the device is intended to administer medicinal products, tissues or cells of human or animal origin, or their derivatives,	Yes	**Partially relevant** Governed by 2001/83/EC. Warnings, contra-indications etc. covered in relevant SmPC (PIL) section. Only to extent device-specific warnings or precautions are included in IFU.	ISO 23908 ISO 11608-1	IFU

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	or biological substances, any limitations or incompatibility in the choice of substances to be delivered • warnings, precautions and/or limitations related to the medicinal substance or biological material that is incorporated into the device as an integral part of the device • precautions related to materials incorporated into the device that contain or consist of CMR substances or endocrine-disrupting substances, or that could result in sensitisation or an allergic reaction by the patient or user				

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	General Safety and Performance Requirements of the Medical Devices Regulation 2017/745	Applicable (Yes or No)	Justification (if needed)	Method of Conformity (Standard / Regulation / Pharmacopoeias)	Evidence of Conformance
23.4 cont.	(t) in the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body, warnings and precautions, where appropriate, related to the general profile of interaction of the device and its products of metabolism with other devices, medicinal products and other substances as well as contra- indications, undesirable side-effects and risks relating to overdose	No	**Not relevant based on technology.** PFP itself is not composed of a substance or of a combination of substances intended to be introduced into the human body but is only used to administer the medicinal product and requirements of Directive 2001/83/EC are to be applied	Not applicable	Not applicable
23.4 cont.	(u) in the case of implantable devices, the overall qualitative and quantitative information on the materials and substances to which patients can be exposed	No	**Not relevant based on technology.** PFP is not implantable.	Not applicable	Not applicable

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	General Safety and Performance Requirements of the Medical Devices Regulation 2017/745	Applicable (Yes or No)	Justification (if needed)	Method of Conformity (Standard / Regulation / Pharmacopoeias)	Evidence of Conformance
23.4 cont.	(v) warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories and the consumables used with it, if any. This information shall cover, where appropriate: • infection or microbial hazards such as explants, needles or surgical equipment contaminated with potentially infectious substances of human origin • physical hazards such as from sharps. If in accordance with the point (d) of Section 23.1 no instructions for use are required, this information shall be made available to the user upon request.	Yes	**Partially relevant** Governed by 2001/83/EC. Warnings and precautions are covered in relevant SmPC (PIL) section. Only to the extent device-specific warnings or precautions are included in IFU.	ISO 23908 ISO 11608-1	IFU
23.4 cont.	(w) for devices intended for use by lay persons, the circumstances in which the user should consult a healthcare professional	No	**Superseded by Medicinal Product Requirements** Governed by 2001/83/EC	Not applicable	Not applicable
23.4 cont.	(x) for the devices covered by this Regulation pursuant to Article 1(2), information regarding the absence of a clinical benefit and the risks related to use of the device	No	**Superseded by Medicinal Product Requirements** PFP has medical purpose.	Not applicable	Not applicable

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	General Safety and Performance Requirements of the Medical Devices Regulation 2017/745	Applicable (Yes or No)	Justification (if needed)	Method of Conformity (Standard / Regulation / Pharmacopoeias)	Evidence of Conformance
23.4 cont.	(y) date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision of the instructions for use	No	**Superseded by Medicinal Product Requirements** As part of SmPC version control	Not applicable	Not applicable
23.4 cont.	(z) a notice to the user and/or patient that any serious incident that has occurred in relation to the device should be Summarised to the manufacturer and the competent authority of the Member State in which the user and/or patient is established	No	**Superseded by Medicinal Product Requirements** Adverse Event reporting as per 2001/83/EC.	Not applicable	Not applicable
23.4 cont.	(aa) information to be supplied to the patient with an implanted device in accordance with Article 18	No	**Not relevant based on technology.** PFP is not implantable.	Not applicable	Not applicable
23.4 cont.	(ab) for devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended	No	**Not relevant based on technology.** PFP does not incorporate such systems.	Not applicable	Not applicable

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3. Conclusions and Path Forward

This paper has focused on the checklist for fulfillment of the GSPRs in the context of a drug prefilled pen as target product for a single integral drug-device combination. The entire Annex I was assessed and evaluated for applicability to the target product as well as how industry anticipates demonstrating conformity.

In summary, the following conclusions have been drawn:

- It needs to be acknowledged that a defined subset of the GSPRs listed in Annex I, such as the labelling requirements, are superseded by the Medicinal Product Requirements governed by Directive 2001/83/EC and related legislation. Therefore, respective medicinal product requirements will be addressed in the medicinal product dossier and EMA/NCA is given precedence in evaluation and authorization thereof.
- Another significant subset of the GSPRs could be marked as not applicable based on technology of a drug prefilled pen where justified.
- Based on defined product criteria and medicinal product characteristics, some GSPR were outlined as partially relevant wherever this was appropriate.
- In order to avoid negative influence to the critical timing for submissions, it was highlighted that certain evidence of conformance such as the IFU and stability data on assembled syringe as part of the DDC will be provided in a core status and in the version available at the time of the technical documentation submission rather than in a final state.
- Moreover, the terms explanation highlights industry's position on detail in documentation to be provided supporting the evidence of conformance for the applicable GSPR.
- No Common Specification was found applicable at this time that should be taken under consideration in the context of a drug prefilled pen.

This paper has put forward a proposal that industry feels is a suitable approach with regards to the given target product and GSPRs fulfillment to allow a comprehensive review and assessment by the Notified Body. Industry's recommendations on the specific interpretation of the GSPRs is anticipated to satisfy the requirements and to be understood and acknowledged by Notified Bodies. It is anticipated that further discussions will evolve on that topic in order to reach alignment across all stakeholders and to approach this topic in a reasonable effort avoiding redundancies in review and assessment wherever possible.

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References

Additional references other than documented in Tables 2-4 can be found below:

Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement and on the repeal of Directive 71/354/EEC (OJ L 39, 15.2.1980, p. 40).

DIRECTIVE 2011/62/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products (OJ L 174 p.74-87, 01. July 2011).

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