Disclaimer

This is a template and must be adapted according to the requirements of the manufacturer/product. This also applies to the corporate design and any specifications of the manufacturer's quality management.

All contents of this template are based on the current interpretations of the regulatory requirements.

The pre-entered contents must always be critically reviewed, adapted or supplemented in relation to the product. THIS IS NOT A FILL-IN TEMPLATE ONLY.

Further notes on the application of the template

Yellow markings are to be checked and supplemented or adapted.

Yellow marked, italic text parts are optional and have to be checked, completed or adapted accordingly.

Light blue, italicised text parts are content-related notes or examples and are not part of the document, i.e. they can be deleted after inserting the content into the respective section.

Pre-entered standards marked in yellow are harmonised in support of Regulation (EU) 2017/745. Their indication in this list corresponds to the entry of the informative annex of the respective standard. The applicability of each single standard must be checked against the respective medical device.

It should be noted that other standards are applicable to the product concerned and should be supplemented at the appropriate sections. In the case of harmonised standards, it is recommended to take into account the corresponding informative annexes in order to verify the relationship between the standard and the General Safety and Performance Requirements of the Regulation (EU) 2017/745 to be covered.

It is recommended not to indicate the date of issue of the respective standards in this list, but to keep it up to date in a separate document (see 1. endnote).

The evidence of conformity shall be precisely identified. In addition, a reference must be made to the place where this evidence can be found within the complete technical documentation (Regulation (EU) 2017/745 Annex II Section 4 d). One possibility is, for example, to integrate the corresponding applicable section of the technical documentation in the document designation of the evidence of conformity in order to show this interface.

This page is not part of the document and is to be removed.

Logo manufacturer	**General Safety and Performance Requirements (GSPR List)** Product(s) or trade name(s) / *product group/family*	Rev. x.x - Date: YYYY-MM-DD

#	General Safety and Performance Requirements	Applicable (A) / Not applicable (NA)?	Applicable standards or other solutions to meet the requirements [i, ii]	Proof of Conformity	Reason/comment in case of deviation / Justification if not applicable
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.	*A*	*EN ISO 13485* *EN ISO 14971* *ISO TR 24971* *MEDDEV 2.7/1* *EN 62366-1* *ISO TR 20416*	*II_5_Quality Management Manual xy* *II_3_SOP xy* *II_5_Risk management file xy* *II_6_Clinical evaluation xy* *II_5_Usability file xy* *III_PMS documents xy*	*Regarding EN 62366-1: The standard was not fully applied, as...*
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.				

		Applicable	Applicable standards or		Reason/comment in case of
	the following order of priority:				

		Applicable	Applicable standards or		Reason/comment in case of
	intended to be used (design and patient safety), and				

	during transport and storage, for example, through fluctuations of temperature and				

		Applicable	Applicable standards or	Reason/comment in case of
10.	Chemical, physical and biological properties			

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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:				
	(a) the choice of materials and substances used, particularly as regards toxicity and, where relevant, flammability;		EN 285:2015+A1:2021 EN ISO 10993-9:2021 EN ISO 10993-23:2021		
	(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;		EN ISO 10993-9:2021 EN ISO 10993-23:2021		
	(c) the compatibility between the different parts of a device which consists of more than one implantable part;		EN ISO 10993-9:2021		
	(d) the impact of processes on material properties;		EN 285:2015+A1:2021		

#	General Safety and Performance Requirements	Applicable (A) / Not applicable	Applicable standards or other solutions to meet the requirements	Proof of Conformity	Reason/comment in case of deviation /
	the devices. Particular attention shall be paid to tissues exposed to those contaminants and				

		Applicable	Applicable standards or		Reason/comment in case of
	Devices shall be designed and manufactured in such a way as to reduce as far as possible		EN 285:2015+A1:2021		

		Applicable	Applicable standards or	Reason/comment in case of
of Annex VI to Regulation (EC) No 1272/2008				

		Applicable	Applicable standards or		Reason/comment in case of
	pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances				

#	General Safety and Performance Requirements	Applicable (A) / Not applicable (NA)?	Applicable standards or other solutions to meet the requirements [i, ii]	Proof of Conformity	Reason/comment in case of deviation / Justification if not applicable
	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.				
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.		EN 285:2015+A1:2021 EN ISO 14160:2021		
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.		EN 285:2015+A1:2021		
11.	Infection and microbial contamination				
11.1.	Devices and their manufacturing processes shall be designed in such a way as to eliminate				

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		Applicable	Applicable standards or		Reason/comment in case of
	packaging is opened at the point of use. It		EN ISO 11737-2:2020		

		Applicable	Applicable standards or		Reason/comment in case of
	shall maintain the integrity and cleanliness of the product and, where the devices are to be sterilised prior to use, minimise the risk of				

		Applicable	Applicable standards or		Reason/comment in case of
	as required by the applicable conformity assessment procedure under this Regulation.				

		Applicable (Yes / No)	Applicable standards or		Reason/comment in case of
	point (g) of Article 1(6), the following shall apply:				

13.2.	For devices manufactured utilising tissues or cells of animal origin, or their derivatives,				

		Applicable	Applicable standards or	Reason/comment in case of
	lead to unacceptable degradation			

		Applicable (Yes / No)	Applicable standards or		Reason/comment in case of
14.	Construction of devices and interaction with their environment				

		Applicable	Applicable standards or		Reason/comment in case of
	environmental conditions, such as magnetic fields, external electrical and electromagnetic				

		Applicable	Applicable standards or	Reason/comment in case of
	investigations or for the treatment given; and			

	be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe.				

		Applicable	Applicable standards or		Reason/comment in case of
	sufficient accuracy, precision and stability for their intended purpose, based on appropriate scientific and technical methods. The limits of				

	(Revised) Safety and	Applicable (Y / Not	Applicable standards or		Reason/comment in case of
	(1)(b) The operating instructions for devices emitting hazardous or potentially hazardous radiation shall contain detailed information as				

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1i					
1j					
	safety standards for protection against the dangers arising from exposure to ionising radiation.				

		Applicable	Applicable standards or	Reason/comment in case of
	radiation.			

17.3.	Software referred to in this Section that is intended to be used in combination with mobile computing platforms shall be designed				

#	General Safety and	Applicable (A) / Not	Applicable standards or	Proof of Conformity	Reason/comment in case of
	equipped with a means of determining the state of the power supply and an appropriate				

		Applicable (Yes / No)	Applicable standards or		Reason/comment in case of
	equipment in the intended environment.				

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		Applicable	Applicable standards or		Reason/comment in case of
20.	Protection against mechanical and thermal risks				

20.4.	Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy				

		Applicable	Applicable standards or	Reason/comment in case of
21.	Protection against the risks posed to the patient or user by devices supplying energy or substances			

#	General Safety and Performance Requirements	Applicable (A) / Not applicable (NA)?	Applicable standards or other solutions to meet the requirements [i, ii]	Proof of Conformity	Reason/comment in case of deviation / Justification if not applicable
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.				
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.		EN 285:2015+A1:2021		
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.		EN 285:2015+A1:2021		

#	General Safety and	Applicable (A) / Not	Applicable standards or	Proof of Conformity	Reason/comment in case of deviation /
	as needle stick injuries, and				

		Applicable	Applicable standards or		Reason/comment in case of
	information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user,				

		Applicable	Applicable standards or		Reason/comment in case of
	each unit, and/or on the packaging of multiple devices.				

		Applicable	Applicable standards or		Reason/comment in case of
	the extent, and only under the conditions, set out in Regulation (EU) No 207/2012 or in any				

		Applicable	Applicable standards or	Reason/comment in case of
	The label shall bear all of the following particulars:			

		Applicable	Applicable standards or	Reason/comment in case of
	blood or plasma derivative, or			

		Applicable	Applicable standards or		Reason/comment in case of
	(j) where there is no indication of the date until when it may be used safely, the date of		EN 285:2015+A1:2021		

#	General Safety and Performance Requirements	Applicable (A) / Not applicable (NA)?	Applicable standards or other solutions to meet the requirements [i, ii]	Proof of Conformity	Reason/comment in case of deviation / Justification if not applicable
	indication of single use shall be consistent across the Union;				
	(o) if the device is a single-use device that has been reprocessed, an indication of that fact, the number of reprocessing cycles already performe				
	(p) if the device is custom-made, the words 'custom-made device';				
	(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';		EN ISO 15223-1:2021		
	(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				

		Applicable	Applicable standards or	Reason/comment in case of
	manufacturer,			

		Applicable	Applicable standards or		Reason/comment in case of
23.4.	Information in the instructions for use				

	(f) where applicable, information allowing the healthcare professional to verify if the device		EN 285:2015+A1:2021		

	special training, or particular qualifications of the device user and/or other persons;				

	[nn] if the device is supplied non-sterile with the intention that it is sterilised before use, the appropriate instructions for sterilisation;		EN ISO 17664-1:2024		

	shall be based on a specific section of the manufacturer's risk management				

	or other person from unintended radiation during use of the device;				

	— warnings, precautions and/or measures to be taken as regards the risks of interference posed by the reasonably foreseeable				

	contaminated with potentially infectious substances of human origin, and				

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	— 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;				
	(w) for devices intended for use by lay persons, the circumstances in which the user should consult a healthcare professional;				
	(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;				
	(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;		EN 285:2015+A1:2021		
	(z) a notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent				

#	General Safety and	Applicable (A) / Not	Applicable standards or other solutions to meet	Proof of Conformity	Reason/comment in case of deviation /