MDR – General Safety and Performance Requirements

#	Requirement	Standards Applied	Design Documentation	Qualification
EU MDR Annex I, Chapter I, #1				
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.			
2.	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.			
3.	Any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient.			
4.	Risks are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.			
EU MDR Annex I, Chapter I, #2				
5.	Reduce risks as far as possible means the reduction of risks as far as possible without adversely affecting the benefit-risk ratio.			
EU MDR Annex I, Chapter I, #3				
6.	Manufacturers shall establish, implement, document and maintain a risk management system.			

#	Requirement	Standards Applied	Design Documentation	Qualification
7.	Risk management shall be understood as a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic updating.			
8.	(a) risk management plan for each device			
9.	(b) identify and analyze the known and foreseeable hazards associated with each device			
10.	(c) estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse			
11.	(d) eliminate or control the risks referred to in point (c)			
12.	(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			
13.	(f) based on the evaluation of the impact of the information referred to in point (e)			
EU MDR Annex I, Chapter I, #4				
14.	Risk control measures adopted by manufacturers for the design and manufacture of the devices shall conform to safety principles			
15.	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.			
16.	(a) eliminate or reduce risks as far as possible through safe design and manufacture			

#	Requirement	Standards Applied	Design Documentation	Qualification
17.	(b) where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated			
18.	(c) provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users.			
19.	Manufacturers shall inform users of any residual risks			
EU MDR Annex I, Chapter I, #5				
20.	In eliminating or reducing risks related to use error, the manufacturer shall			
21.	(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)			
22.	(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).			
EU MDR Annex I, Chapter I, #6				
23.	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.			

#	Requirement	Standards Applied	Design Documentation	Qualification
EU MDR Annex I, Chapter I, #7				
24.	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.			
EU MDR Annex I, Chapter I, #8				
25.	All known and foreseeable risks, and any undesirable side-effects, shall be minimized 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.			
EU MDR Annex I, Chapter I, #9				
26.	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.			
EU MDR Annex I, Chapter II, #10				

#	Requirement	Standards Applied	Design Documentation	Qualification
27.	Chemical, physical and biological properties			
EU MDR Annex I, Chapter II, #10.1				
28.	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.			
29.	(a) the choice of materials and substances used, particularly as regards toxicity and, where relevant, flammability			
30.	(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			
31.	(c) the compatibility between the different parts of a device which consists of more than one implantable part			
32.	(d) the impact of processes on material properties			
33.	(e) where appropriate, the results of biophysical or modelling research the validity of which has been demonstrated beforehand			
34.	(f) the mechanical properties of the materials used, reflecting, where appropriate, matters such as strength, ductility, fracture resistance, wear resistance and fatigue resistance			
35.	(g) surface property			
36.	(h) the confirmation that the device meets any defined chemical and/or physical specifications			
EU MDR Annex I, Chapter II, #10.2				

#	Requirement	Standards Applied	Design Documentation	Qualification
37.	Devices shall be designed, manufactured and packaged in such a way as to minimize 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.			
EU MDR Annex I, Chapter II, #10.3				
38.	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.			
EU MDR Annex I, Chapter II, #10.4				
39.	Substances			
EU MDR Annex I, Chapter II, #10.4.1				

#	Requirement	Standards Applied	Design Documentation	Qualification
40.	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.			
41.	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 store such medicines, body fluids or substances, including gases, to be (re)administered to the body,			
42.	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			
43.	(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 (1), or			

#	Requirement	Standards Applied	Design Documentation	Qualification
44.	(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 (2) 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 (3), in accordance with the criteria that are relevant to human health amongst the criteria established therein.			
EU MDR Annex I, Chapter II, #10.4.2				
45.	Justification regarding the presence of CMR and/or endocrine-disrupting substances The justification for the presence of such substances shall be based upon:			
46.	an analysis and estimation of potential patient or user exposure to the substance;			
47.	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;			

#	Requirement	Standards Applied	Design Documentation	Qualification
48.	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; and			
49.	where applicable and available, the latest relevant scientific committee guidelines in accordance with Sections 10.4.3. and 10.4.4.			

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017