Guidance Document:

Clinical Evaluation Pathways MDR 2017/745

DISCLAIMER:

1. This document is for informational purposes only. NSAI assumes no responsibility for the accuracy or completeness of information within this document. It does not purport to be comprehensive or render professional advice, hence, we bear no responsibility for any decision(s) made by the readers of this document. It is not a substitute for the information provided in MDR and the relevant MDCG guidance documents, which should be used as the key documents when planning the clinical evaluation route for your device.

2. Applicable devices given for each clinical evaluation route are listed as per the MDR and MDCG 2020-6. There may be other classes of devices not listed that can be applied to other clinical evaluation routes. The onus is on the manufacturer to review the MDR and the guidance documents and choose which route can be correctly applied to their device type. NSAI will review in accordance with the requirements of the MDR and MDCG guidance documents.

Clinical Evaluation Route options	Requirement	Applicable devices
Article 61(3)	a) Equivalence route b) Clinical Investigations **AND** c) Alternative treatment options (cannot claim only option c)	All devices -Non-Legacy or some legacy devices that do not have sufficient clinical evidence, brand new devices under MDR

Clinical Evaluation Route options	Requirement	Applicable devices
Article 61(4)	Exception for Implantable and class III devices who do not want to performa clinical investigation: -Manufacturer has made modifications to a device, which they have alreadymarketed (under the directives or regulation) -Can claim equivalence to a device marketed by the same Manufacturer -Notified Body agrees with equivalence claim -Clinical evaluation of the marketed device is sufficient to demonstrateconformity to the GSPRs (CER of the marketed MDR compliant) -Manufacturers must perform a PMCF study and show NSAI the plan (whichshould include a study) to demonstrate safety and performance of the device to be CE marked	Implantable and class III devices only **NOTE: This requirement cannot be applied to low-risk devices**

Article 61(5)	Exception for Implantable and class III devices who do not want to performa clinical investigation: -Manufacturers can claim equivalence to a different device that they don't manufacture themselves, however it must be CE- Marked under the MDR - Provide a contract in place that explicitly allows the Manufacturers of the2nd device full access to the technical documentation of the equivalent device on an ongoing basis - The original clinical evaluation has to be performed in accordance with therequirements of the MDR (CER of the equivalent device must be MDR compliant) - Manufacturer needs to provide clear evidence of this to NSAI	Implantable and class III devices only **NOTE: This requirement cannot be applied to low-risk devices**

Article 61(6a)	Exception for manufacturers of legacy implantable and class III devices whodo not want to perform a clinical investigation: -Need to base the clinical evaluation on sufficient clinical data (as per MDCG2020-6) -Compliant to the relevant product specific common specification (CS) where such a CS is available (In the absence of CS, Manufacturers will needto prove sufficient clinical evidence) **Note: If a Manufacturers claims article 61 (6a & 6b) and no CS exists at thetime of CE marking, and the relevant CS becomes available or released post CE marking, the manufacturer must update their technical documentation to comply with the relevant common specifications or run the risk of losing the CE mark**	Legacy Implantable and class III devices only **NOTE: This requirement cannot be applied to low-risk devices**

Article 61(6b)	If your device is a suture, staple, dental filling, dental braces, tooth crowns,screws, wedges, plates, wires, pins, clips, connectors, -Manufacturers must base their clinical evaluation on sufficient clinicaldata (as per MDCG 2020-6) -Manufacturers must be compliant with the relevant CS -Compliant to the relevant product specific CS where such a CS is available(In the absence of CS, Manufacturers will need to prove sufficient clinical evidence)	WET devices
Article 61(9)	For devices with no medical purpose (Annex XVI devices) -The requirement to demonstrate a clinical benefit in accordance with thisChapter and Annexes XIV and XV shall be understood as a requirement to demonstrate the performance of the device. -Clinical evaluations of those products shall be based on relevant data concerning safety, including data from post-market surveillance, PMCF, and,where applicable, specific clinical investigation. -Clinical investigations shall be performed for those products unless relianceon existing clinical data from an analogous medical device is duly justified. NOTE: As per the regulation (Article 61(9)), a manufacturer may	Annex XVI devices only

	either perform a clinical investigation for these Annex XVI devices or claim relianceon an analogous medical device.	
Article 61(10)	Where the demonstration of conformity with general safety andperformance requirements based on **clinical data is not deemed appropriate, the Manufacturers shall provide:** -Adequate justification which is based on the results of the manufacturer's risk management and on consideration of the specifics of the interaction between the device and the human body, the clinical performance intendedand the claims of the manufacturer. -The manufacturer shall duly substantiate in the technical documentation referred to in Annex II why it considers a demonstration of conformity withgeneral safety and performance requirements that is based on the results of non-clinical testing methods alone, including performance evaluation, bench testing and pre-clinical evaluation, to be adequate. - This will be considered only for low-risk devices, with no clinical benefit, hence the device does not have a positive impact on the health of an individual, expressed in terms of a meaningful, measurable, patient- relevant clinical outcome(s), including outcome(s) related to diagnosis, or a positive impact on patient management or public health, Examples of devices that may be considered under this article are a lab fridge, a lab scalefor weighing or measuring blood products, etc.	Only for low-risk devices where there is no clinical benefit. **NOTE: This requirement cannot be applied to class III & Implantable devices**

MDCG 2020-6	For Legacy Devices [this is considered to include all devices previously CE marked under the European Medical Devices Directive 93/42/EEC (MDD) or Active Implantable Medical Devices Directive 90/385/EEC (AIMDD)] Manufacturers of Legacy devices should consider applying the requirements of MDCG 2020-6, including the suggested hierarchy of clinical evidence for confirmation of conformity with relevant GSPRs under the MDR, seen in appendix III.	Legacy devices only **NOTE: This guidance cannot be applied to non-legacy devices**
MDCG 2020-6 Section 1.2	Legacy devices claiming WET must fulfil the following criteria below, by providing detailed rationale why the device fulfils these criteria and must provide supporting documents to justify the rationale given for each criterion (all 4 criteria must be fulfilled) The common features of the devices which are well-establishedtechnologies are that they all have: • Relatively simple, common and stable designs with little evolution	Legacy devices claiming WET only

	• Their generic device group has well-known safety and has not beenassociated with safety issues in the past • Well-known clinical performance characteristics and their genericdevice group are standard of care devices where there is little evolution in indications and the state of the art • A long history in the market. Manufacturers must base their clinical evaluation on sufficient clinical evidence (as per MDCG 2020-6) -Manufacturers must be compliant with the relevant CS where such a CS is available (In the absence of CS, Manufacturers will need to prove sufficient clinical evidence) **NOTE 1:** A manufacturer that claims that a device qualifies as a WET devicemust specify what level of evidence has been provided based on MDCG 2020-6, appendix III table. **Reliance solely on complaints and vigilance is not sufficient.** **NOTE 2:** If a Manufacturers claims WET (as per MDCG section 1.2) and no CS exists at the time of CE marking, and the relevant CS becomes available or released post CE marking, the manufacturer must update their technical documentation to comply with the relevant common specifications or run the risk of losing the CE mark.	

Important Information to be Considered Prior To Submission of Application

1. **As per MDCG 2020-6**, legacy devices which have been placed on the market have been subjected to conformity assessment and therefore are presumedto have been supported by clinical data. Post market clinical data together with the clinical data generated for the conformity assessment under the MDD/AIMDD will be the basis of the clinical evaluation process for legacy devices under the MDR, hence manufacturers must also state what clinical evaluationroute (equivalence and/or clinical investigation) was used during the initial conformity assessment (when the device was first CE marked) under the directives. If the clinical evaluation route during the initial conformity assessment was based on equivalence, as per MDCG 2020-6 Section 5, page 9 of 22, the European Commission guidance MEDDEV 2.12/2 regarding PMCF also notes that in the case where the clinical evaluation was based exclusively on clinical data from equivalent devices for initial conformity assessment, the certifying notified body shall verify that **PMCF studies** have been conducted. NSAI will assess this for all Legacy devices which previously claimed equivalence during their initial assessment.

2. **As per MEDDEV 2.12/2** all MDR new application (Not Legacy devices) claiming equivalence need to provide a PMCF study plan. Please ensure to include PMCF clinical study plan in your submission.