Table: Responsibilities and roles of Notified Bodies according to the EU Medical Device Regulation (2017/745)

CHAPTER I – SCOPE AND DEFINITIONS
Notified Body means a conformity assessment body designated in accordance with REGULATION (EU) 2017/745 as per Art. 2.42.
CHAPTER II – MAKING AVAILABLE ON THE MARKET AND PUTTING INTO SERVICE OF DEVICES, OBLIGATIONS OF ECONOMIC OPERATORS, REPROCESSING, CE MARKING, FREE MOVEMENT
NB should interact with all stakeholders including Manufacturers, Authorized Representatives and Importers about vigilance data, status and relative changes (Art. 10, 11 and 13). Art. 17 describes the involvement of NB to verify compliance with applicable standards for reprocessing, considered as a high-risk process. Finally, Art. 20 clarifies that the NB responsible for issuing a CE certificate and subsequently placing a device on the market must be clearly identifiable not only on the packaging but also on all the information material accompanying the device, alongside the CE mark.
CHAPTER III – IDENTIFICATION AND TRACEABILITY OF DEVICES, REGISTRATION OF DEVICES AND OF ECONOMIC OPERATORS, SUMMARY OF SAFETY AND CLINICAL PERFORMANCE, EUROPEAN DATABASE ON MEDICAL DEVICES
NB are directly involved also in the requirement for devices to be traceable, including a reference to the Basic UDI-DI (unique device identification) on the certificate issued, assessing and validating the draft of the summary of safety and clinical performance as part of the documentation submitted by manufacturers of implantable devices and class III devices, and tracking their activity on Eudamed (Art. 29, 32 and 33).
CHAPTER IV - NOTIFIED BODIES
NB are designated and monitored by Members States, using an Authority responsible for notified bodies that can be different from the Competent Authority safeguarding the objectivity and impartiality. NB designated must meet precise requirements including quality management requirements, economic, technical and administrative resources, and having competent personnel defined by pre-established criteria, and they must provide evidence about any relationship with Subsidiaries and subcontracting. The designation process is performed by experts qualified in the assessment of conformity assessment bodies in the field of medical devices who are nominated by the Member States and the Commission. When the NB is notified under several European Union acts, it gets a single identification number. NB assessment activities are monitored by the Authority responsible for notified bodies, which can challenge its competence and modify its designation. NBs cooperate amongst themselves and publish their standard fees (Art. 35-50).

CHAPTER V - CLASSIFICATION AND CONFORMITY ASSESSMENT
Prior to placing a device on the market or putting it into service, manufacturers shall undertake an assessment of conformity in accordance with Regulation (EU) 2017/745 based on the risk class of the device. For devices classified as Is, Im, Ir, IIa, IIb and III, the involvement of NB is mandatory and differs according to the device category and class of risk. Any dispute between the manufacturer and the notified body concerned, arising from the application of classification rules, shall be referred for a decision to the competent authority of the Member State in which the manufacturer has its registered place of business. NB may require from the manufacturer any information or data which is necessary in order to properly conduct the chosen conformity assessment procedure. In case of class III implantable devices and class IIb active devices intended to administer and/or remove a medicinal product, the NB shall inform its Competent Authority and share its clinical evaluation assessment report, by digital platform, with an Expert Panel. The European Commission shall draw up an annual overview of devices which have been subject to this consultation procedure and a listing of the cases where the notified body did not follow the advice from the expert panel. Notified bodies may impose restrictions to the intended purpose of a device to certain groups of patients or require manufacturers to undertake specific PMCF (post-market clinical follow-up) studies giving the reason for its decision. In cases where a manufacturer terminates its contract with a notified body and enters into a contract with another notified body in respect of the conformity assessment of the same device, the detailed arrangements for the change of notified body shall be clearly defined in an agreement between the manufacturer, the incoming notified body and, where practicable the outgoing notified body. The outgoing notified body shall withdraw the certificates it has issued for the device concerned on the date on which they become invalid (Art. 51-60).
CHAPTER VI - CLINICAL EVALUATION AND CLINICAL INVESTIGATIONS
Confirmation of conformity with relevant general safety and performance requirements set out in Annex I under the normal conditions of the intended use of the device, and the evaluation of the undesirable side-effects and of the acceptability of the benefit-risk ratio referred to in Sections 1 and 8 of Annex I, shall be based on clinical data providing sufficient clinical evidence, including where applicable relevant data as referred to in Annex III. In the case of implantable devices and class III devices, clinical investigations shall be performed, with specific exclusion criteria: in this case, NB shall check that the PMCF plan is appropriate and that it includes post-market studies to demonstrate the safety and performance of the device, and it shall justify in its assessment report the rationale to apply this criterion.

Clinical investigations shall be designed, authorised, conducted, recorded and reported in accordance with the provisions of Regulation (EU) 2017/745, where carried out as part of the clinical evaluation for conformity assessment purposes, for specific purposes. The ethical review shall be performed by an ethics committee in accordance with national law and specific conditions that shall be met (Art. 61-82).

CHAPTER VII - POST-MARKET SURVEILLANCE, VIGILANCE AND MARKET SURVEILLANCE

Post-market activities are clearly distinguished in three categories (Art. 83-100). The NB is involved differently in each of them:

- **Post-market surveillance** means all activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market, or put into service, for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions. NB shall assess the correctness and consistency of the quality management system of manufacturer, plan and procedure to collect data. It shall also verify the correct management of collected data, consistency between the technical file, procedure, plan and report, and confirm the compliance with essential requirements.
- **Vigilance** is composed by all information that the manufacturer collects and reports to the relevant Competent Authorities relative to serious incidents involving devices, except for any expected side-effects which are clearly documented in the product information and quantified in the technical documentation and are subject to trend reporting, along with any field safety corrective action that it institutes. Where a competent authority of a Member State obtains such reports on suspected serious incidents from healthcare professionals, users or patients, it shall take the necessary steps to ensure that the manufacturer of the device concerned is informed of the suspected serious incident without delay. NB could be informed as observer and consider if some action about the surveillance process, technical assessment, issued certificate or any action considered adequate should take place.
- **Market surveillance** include all activities carried out and measures taken by competent authorities to check and ensure that devices comply with the requirements set out in the relevant European Union harmonisation legislation and that they do not endanger health, safety or any other aspect of public interest protection. The NB is always informed by the Competent Authority through Eudamed about issues that have been identified, the action it intends to take and the information that the economic operator involved has provided to the Competent Authority.

CHAPTER VIII - COOPERATION BETWEEN MEMBER STATES, MEDICAL DEVICE COORDINATION GROUP (MDCG), EXPERT LABORATORIES, EXPERT PANELS AND DEVICE REGISTERS

The MDCG is among the actors involved in the evaluation of NB as per Section IV, and it contributes to the development of guidance aimed at ensuring effective and harmonised implementation of Regulation (EU) 2017/745, regarding application of the general safety and performance requirements and conduct of clinical evaluations and investigations by manufacturers, assessment by NB, and vigilance activities. Clinical assessment of NB is also guided from

Expert Panel activities aimed at contributing to the development of and reviewing clinical evaluation guidance and performance evaluation guidance in line with the state of the art. NB and Expert Panels are also involved in the Clinical Evaluation Consultation Procedure (Art., 106).
CHAPTER IX - CONFIDENTIALITY, DATA PROTECTION, FUNDING AND PENALTIES
NB exchanges information and disseminates security alerts with Member States and the Commission, while respecting confidentiality obligations and applying the Data Protection Directive 95/46/EC (Art. 109, 110).
CHAPTER X - FINAL PROVISIONS
NB shall apply MDR requirement about Post- Market assessment also for devices marketed under MD 93/42/EC Directive (Art. 120).
ANNEX I - GENERAL SAFETY AND PERFORMANCE REQUIREMENTS
The function of NB is to verify or confirm compliance to safety and performance requirement during its assessment activities and before issuing CE certification.
ANNEX II - TECHNICAL DOCUMENTATION
When NB perform the technical conformity assessment, the manufacturer shall provide technical documentation and summary in a clear, organised, readily searchable and unambiguous manner, including in particular the elements listed in this Annex.
ANNEX III - TECHNICAL DOCUMENTATION ON POST-MARKET SURVEILLANCE
When NB perform the *post-market* conformity assessment, manufacturer shall provide technical documentation and summary in a clear, organised, readily searchable and unambiguous manner, including in particular the elements listed in this Annex.
ANNEX IV - EU DECLARATION OF CONFORMITY
In the case of class Is, Ir, Im, IIa, IIb and III devices, the Declaration of Conformity, along with other requirements, shall report the NB number and data. This document is a part of the NB assessment.

ANNEX V - CE MARKING OF CONFORMITY
The format of CE marking reported on the label and other technical documents, is also reviewed as part of the NB conformity assessment.
ANNEX VI - INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF DEVICES AND ECONOMIC OPERATORS IN ACCORDANCE WITH ARTICLES 29(4) AND 31, CORE DATA ELEMENTS TO BE PROVIDED TO THE UDI DATABASE TOGETHER WITH THE UDI- DI IN ACCORDANCE WITH ARTICLES 28 AND 29, AND THE UDI SYSTEM
During the assessment, NB shall verify consistency between information reported in Technical documentation and in the UDI Database.
ANNEX VII - REQUIREMENTS TO BE MET BY NOTIFIED BODIES
Each NB shall be established under the national law of a Member State, or under the law of a third country with which the European Union has concluded an agreement in this respect. It shall comply with organisational and general requirements about legal status and organisational structure, independence and impartiality, confidentiality, liability, financial requirements, and participation in coordination activities. Quality management requirements shall also be met as well as resource requirements about roles, competences and contracts with personnel. Moreover, NB shall have in place documented processes and sufficiently detailed procedures for the conduct of each conformity assessment activity for which it is designated, including the individual steps from pre-application activities up to decision-making and surveillance and taking into account, when necessary, the respective specificities of the devices: all process requirements shall be met.
ANNEX VIII - CLASSIFICATION RULES
NB shall verify that the rationale for the risk classification is consistent with intended use, device characteristics, risk assessment and technical documentation including clinical evaluation, and correctly described by rule application and in a related discussion.
ANNEX IX - CONFORMITY ASSESSMENT BASED ON A QUALITY MANAGEMENT SYSTEM AND ON ASSESSMENT OF TECHNICAL DOCUMENTATION
Annex IX includes the assessment of the manufacturer’s Quality management system, technical documentation including clinical evaluation, and administrative provisions. Based on risk class, the NB assessment activity includes full application of these aspects for class III devices; application only of

Chapters I and III and Chapter II point 4 for class IIb and IIa devices; for class IIa the alternative application of only Chapters I and III of this Annex but with the addition of a conformity assessment compliant with Annex XI point 10 or 18; and finally for class Is, Ir, Im devices, it includes only Chapters I and III.
ANNEX X - CONFORMITY ASSESSMENT BASED ON TYPE-EXAMINATION
EU type-examination is the procedure whereby a notified body ascertains and certifies that a device, including its technical documentation and relevant life cycle processes and a corresponding representative sample of the device production envisaged, fulfils the relevant provisions of this Regulation. NB conformity assessment can be applied to class IIb devices in addition to Annex XI requirements.
ANNEX XI - CONFORMITY ASSESSMENT BASED ON PRODUCT CONFORMITY VERIFICATION
Annex XI is composed by Part A (production quality assurance) and Part B (product verification). NB can perform this assessment for class IIb devices in association with Annex X. For class I devices, it is necessary to consider only Part A in association with Annex X.
ANNEX XII - CERTIFICATES ISSUED BY A NOTIFIED BODY
NB shall issue CE certificate based on general and minimum requirements.
ANNEX XIII - PROCEDURE FOR CUSTOM-MADE DEVICES
NB shall perform assessment for custom-made devices in compliance with this annex.
ANNEX XIV - CLINICAL EVALUATION AND POST-MARKET CLINICAL FOLLOW-UP
NB shall perform assessment of manufacturer’s clinical evaluation and of the post-market follow-up considering all aspect and documentation requirements reported in this Annex.
ANNEX XV - CLINICAL INVESTIGATIONS
NB shall assess the adequacy of results consistent with the main aspects of the technical file and formal submitted documents; adequacy of method, general requirements and sponsor responsibility is verified by the Competent Authority.

ANNEX XVI - LIST OF GROUPS OF PRODUCTS WITHOUT AN INTENDED MEDICAL PURPOSE REFERRED TO IN ARTICLE 1(2)
Considering devices listed in this Annex, the requirement to demonstrate a clinical benefit in accordance with this Chapter and Annexes XIV and XV shall be understood as a requirement to demonstrate the performance of the device.

This summary was prepared for the CORE-MD consortium by members of Team NB, in July 2021.

The relevant sections of the legal text in the Medical Device Regulation can be found in full at:

European Union. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. *http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.117.01.0001.01.ENG&toc=OJ:L:2017:117:TOC*