Team-NB Position Paper list (update November 8th 2026)

Date	Name		Version	Status
03-11-26	Team-NB-PositionPaper-Role_and_Experience_of_Expert_Panels_unde_Article 54_MDR-1-20261103	Team-NB members endorsed the paper, drawing on their shared experience of five years of the Clinical Evaluation Consultation Process (CECP) under Article 54 of the MDR. With discussions on the current revision of the MDR underway, the CECP remains a critical step in supporting the introduction and acceptance of novel, innovative high-risk medical devices in Europe. The paper also sets out recommendations from Team-NB members on how the process could be improved through collaboration with all key stakeholders.	V1	Active
06-10-26	Team-NB-PositionPaper-IVDR-Certification-Process-Consensus-Document-V2	The paper is describing in detail pre-application and application and Post application phases processes through which manufacturers may apply to Notified Bodies (NBs) for the certification of medical devices under the regulation (EU) 2017/746 (IVDR).	V2	Active
06-08-26	Team-NB-PositionPaper-Transparency-V1	Position Paper on Transparency in the framework of the MDR/IVDR proposed revision of the Regulations	V1	Active
15-07-26	Team-NB-PositionPaper-MDR-Certification-Process-Consensus-Document-V2	The paper is addressing to describe in detail the pre-application, application processes through which manufacturers may apply to Notified Bodies (NBs) for the certification of medical devices under the regulation (EU) 2017/745 (MDR).	V2.1	Active
30-06-26	Team-NB-PositionPaper-MDR-Update-Risk-adaptive-surveillance-V1	MDR - complementary Proposal for risk adaptive surveillance system	V1	Active
30-06-26	Team-NB-PositionPaper-IVDR-Update-Risk-adaptive-surveillance-V1	IVDR - complementary Proposal for risk adaptive surveillance system	V1	Active
16-06-26	Team-NB-PositionPaper-Micro-Small-Entreprise-Initiatives-V1	Micro and small manufacturers supported by Team-NB thanks to their trainings and proposed measures.	V1	Active
10-06-26	Team-NB-PositionPaper-IVDR-Application-and-appropriate-surveillance-Transfer-agreement-V1	Excel Position Paper on IVDR Application and appropriate surveillance Transfer agreement	V1	Active

21-04-26	Team-NB-PositionPaper-Article61-10-V1	Clinical Evaluation Based on Non-Clinical Data: EU Medical Device Regulation 2017/745 Article 61.10	V1	Active
21-04-26	Team-NB-PositionPaper-BPG-TechnicalDocEU-MDR-2017-745-V4	Best Practice Guidance for the Submission of Technical Documentation under Annex II and III of Medical Device Regulation (EU) 2017/745	V4	Active
16-02-26	Team-NB-PositionPaper-Demonstration-of-Safety-and-Performance-for-Combinatorial-Use-of-Devices-or-Equipment-V1	The purpose of this paper is to provide guidance on how a manufacturer should demonstrate Safety and Performance when they claim that their reagent can be used on other instruments.	V1	Active
16-12-25	Team-NB-PositionPaper-Annex-VII-V1	The paper is addressing Annex VII - Implementing Regulation Draft	V1	Active
12-12-25	Team-NB-PositionPaper-IVD-SARS-CoV-2-down-classification-V1	Considerations for conformity assessments in the case of down classification of SARS-CoV-2 tests, including operational aspects and Q&A parts.	V1	Active
22-10-25	Team-NB-PositionPaper-IVDR-Significant-changes-V2	Significant changes according to Article 110 (3) of Regulation EU 2017/746	V2	Active
22-10-25	Team-NB-PositionPaper-MDR-Application-and-appropriate-surveillance-Transfer-agreement-V1	Template agreement form related to the transfer of mdr formal application and of appropriate surveillance of legacy devices (legacy devices).	V1	Active
03-09-25	Team-NB PositionPaper-BPG-technicalDoc EU-IVDR-2017-746-V2	Best Practice Guidance for the Submission of Technical Documentation under Annex II and III of In Vitro Diagnostic Medical Devices Regulation	V2	Active
17-07-25	Team-NB-PositionPaper-Orphan-IVDR-Medical-Devices-V1	The paper is addressing Orphan under the IVDR	V1	Active
27-06-25	Team-NB-PositionPaper-Software-Qualification-under-the-IVDR-V2	The paper is addressing Software qualification under the IVDR.	V2	Active
09-04-25	Team-NB-PositionPaper-EU-AI-Act-V2	The designation of notified bodies under the upcoming Artificial Intelligence Act	V2	Active
10-12-24	Joint-Team-NB-IG-NB-PositionPaper-AI-in-MD-Questionnaire-V1.1	This questionnaire was prepared in accordance with MDGG 2022-14 requests.	V1.1	Active
11-09-24	Team-NB-PositionPaper-IVD-Transfer-Agreement	The paper is proposing a form for a contract between the 3 involved parties.	V1	Active
10-07-24	Team-NB-IVDConfirmationLetterTemplate-V2	The paper is proposing an updated version of the IVD Confirmation Letter template specific to IVD on the basis of the MD one.	V2	Active

02-07-24	Team-NB-PositionPaper-TransferAgreement_v02	Transfer Agreement for Surveillance of Legacy Devices specifying the terms of the transfer of the appropriate surveillance according to Regulation (EU) 2017/7451	V2	Active
19-02-24	Team-NB-PositionPaper-Classification-of-SARS-Cov2	The paper is addressing the reclassification of Covid-19 devices.	V1	Active
15-12-23	Team-NB-PositionPaper-Lifetime-Medical-Device	MD Lifetime is addressing Lifetime with the objective to consider different device types of a medical device lifetime in terms of safe and effective use.	V1	Active
11-08-23	Team-NB-PositionPaper-LegacyMD-Surveillance-Transfer-Agreement-V1-20230811		V1	Active
10-08-23	Team-NB-PositionPaper-MDRTransitionTimelines-NotifiedBodyCapacity-V1	Views on the amended timelines with regards to benefits for the European patients and as the continuity in the availability of essential medical devices in the European market	V1	Active
10-07-23	Team-NB-PositionPaper-NB-ConfirmationLetterEU2023-607-V2	Template for notified body confirmation letter of the status of a formal application in the framework of Regulation EU 2023/607	V2	Active
16-05-23	Team-NB PositionPaper HybridAudits V2	Notified bodies' paper on the application of hybrid audits to quality management system assessments under MDR/IVDR	V2	Active
11-11-22	Team-NB PositionPaper Certificates under conditions-V1	Team NB Position in Response to MDCG 2022-14 Item Number 17 – 'Certificates under Conditions'	V1	Active
05-10-22	Team-NB-PositionPaper-VoluntaryTransfer-Agreement-V1-20221005	Transfer Agreement specifying the terms of voluntary change of notified body under Regulation (EU) 2017/745 or Regulation (EU) 2017/746	V1	Active
05-10-22	Team-NB PositionPaper CyberSecurity-V1	Recommendations to cybersecurity harmonised	V1	Active
05-10-22	Team-NB PositionPaper Off Label Use-V1	Data generated from 'Off-Label' Use of a device under the EU Medical Device Regulation 2017/745.	V1	Active
14-07-22	Team-NB-PositionPaper ConfAssessment-Multiplex IVD V1	Notified body approach for the Technical Documentation assessment approach of multiplex in-vitro diagnostic devices	V1	Active
28-01-22	Team-NB-PositionPaper-ModificationsSamplingPlan-V1	Team-NB Notified Bodies recommendations on the handling of modifications to the device sampling plans	V1	Active

01-12-21	Team-NB-PositionPaper-on-MDR_IVDR-Implementation-V3	Notified Body position paper on MDR/IVDR Implementation	V3	Active
06-10-21	Team-NB-PositionPaper-Article117-NB-Opinion-Template-V1	Proposal for a Notified Body Opinion Template	V1	Active
06-10-21	Team-NB-PositionPaper-Artificial-Intelligence-V1	European Artificial Intelligence Regulation	V1	Active
20-07-21	Team-NB-PositionPaper-ImplantCard-20210720	Team-NB Position Paper on a risk-based approach for medical devices exempted from an implant card and information to be supplied to the patient with an implanted device per Article 18.3	V1	Active
19-05-21	Team-NB-PositionPaper-ClassD-20210519-V4.4	Team-NB Notified Bodies considerations on conformity assessment for class D devices	V4.4	Active
21-12-20	Team-NB PositionPaper Art117 Substantial Changes DrugDeviceCombination	Position paper for the interpretation of device related changes in relation to a Notified Body Opinion as required under Article 117 of Medical Device Regulation (EU)2017/745	V1	Active
18-11-20	Team-NB-PositionPaper-RemoteAudits-V1-20201118	Position paper Remote Audit Survey : Analysis	V1	Active
22-07-20	Team-NB Position Paper Technical Cooperation Program TCP III -V1	Position Paper on the requirements for the EU MDR/IVDR Notified Body Partners under the Technical Cooperation Program on Exchange of Medical Device Quality Management System Regulation and ISO 13485 Audit Reports (TCP III)	V1	Active
01-04-20	Team-NB Position-Paper Documentation Requirements Article117 V1	Position Paper on Documentation Requirements for Drug Device Combination Products falling in the Scope of Article 117 of MDR 2017/745.	V1	Active

Legend Status: active / worked on /voting process /under revision