Team-NB Position Paper list (update September 11th 2024)

Date	Name		Version	Status
25-11-24	Team-NB-PositionPaper-AI-in-MD-Questionnaire-V1-20241125	This questionnaire was prepared in accordance with MDGG 2022-14 requests.	V1	Active
11-09-24	Team-NB-PositionPaper-IVD-Transfer-Agreement-20240911	The paper is proposing a form for a contract between the 3 involved parties.	V1	Active
10-07-24	Team-NB-IVDConfirmationLetterTemplate-V2-20240710	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_v02-20240702	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-Cov2-20240202	The paper is addressing the reclassification of Covid-19 devices.	V1	Active
15-12-23	Team-NB-PositionPaper-Lifetime-Medical-Device-20231127	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
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
19-04-23	Team-NB-PositionPaper BPG TechnicalDoc EU-MDR-2017-745-V2	Best Practice Guidance for the Submission of Technical Documentation under Annex II and III of Medical Device Regulation (EU) 2017/745	V2	**under revision**

25-02-23	Team-NB PositionPaper-BPG-technicalDoc EU-IVDR-2017-746 V1	Best Practice Guidance for the Submission of Technical Documentation under Annex II and III of In Vitro Diagnostic Medical Devices Regulation	V1	Active
16-12-22	Team-NB PositionPaper AI Designation-V1	The designation of notified bodies under the upcoming Artificial Intelligence Act	V1	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 ConformityAssessmentClassD V1	Class D measures in the absence of EU Reference Laboratories- Points to consider for Notified Body approach	V1	Active
05-10-22	Team-NB PositionPaper CyberSecurity-V1	Recommendations to cybersecurity harmonised approach	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
03-10-22	Team-NB-PositionPaper-Leveraging-evidence-from-Directives-DRAFT	Leveraging directive conformity assessments to establish compliance with the MDR requirements	V1	worked on
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
09-11-21	Team-NB-PositionPaper-IVDR-Significant changes-V1	Significant changes according to Article 110 (3) of Regulation EU 2017/746	V1	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
11-03-20	Team-NB-Position paper on Dental Implants-20200311-V1	Position Paper on Applicability of exemption rule to endosseous dental implants and dental implant abutments	V1	under revision

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