Team-NB Position Paper list (update April 24th, 2023)

Date	Name	Scope/description	Version	Status
19-04-23	Team-NB-PositionPaper-BPG-TechnicalDocEU-MDR-2017-745-V2-20230419	Best Practice Guidance for the Submission of Technical Documentation under Annex II and III of Medical Device Regulation (EU) 2017/745	V2	Active
01-10-22	Team-NB-PositionPaper-BPG-TechnicalDoc-IVDR-2017-746	Best Practice Guidance for the Submission of Technical Documentation against IVDR (EU) 2017/746	V1	worked on
28-11-22	Team-NB-PositionPaper-Certificates_under_conditions-V1-20221128	Team NB Position in Response to MDCG 2022-14 Item Number 17 – 'Certificates under Conditions'	V1	Active
17-10-22	Team-NB-PositionPaper-AI-Designation-V1	The designation of notified bodies under the upcoming Artificial Intelligence Act	V1	Active
05-10-22	Team-NB-PositionPaper-TransferAgreement-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-InterimmeasuresVerifclassD-V1-20221005	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-V1-20221005	Cybersecurity	V1	Active
05-10-22	Team-NB-PositionPaper-Off-LabelUse-V1-20221005	Data generated from 'Off-Label' Use of a device under the EU Medical Device Regulation 2017/745.	V1	Active
05-10-22	Team-NB-PositionPaper-BPG-TechnicalDocEU-MDR-2017-745-V1-20221005	Best Practice Guidance for the Submission of Technical Documentation under Annex II and III of Medical Device Regulation (EU) 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
28-06-22	Team-NB-PositionPaper-Transition-for-Guidances-Standards-BestPracticeDocs-V1	Notified Body position paper on transitional period for implementation of MDCG guidances and best practice documents	v1	Active

26-09-22	Team-NB-PositionPaper-HybridAudits-V1-20220926	Notified bodies' paper on the application of hybrid audits to quality management system assessments under MDR/IVDR	v1	Active
14-07-22	Team-NB-PositionPaper-ConfAssessment-Multiplexassays-V120220714	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-202107020	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-NBPosition-Paper-Art117SubChangeLifeCycleMngt-202012	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- TCP-V1-20200720	Team NB position statement 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_on-Documentation-Requirements-Article117-V1-20200401	Team-NB 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	Active
09-01-20	TEAM NB-NB Med Position on Dental Implants - Comments_Meeting 20200128	Position Paper on Applicability of exemption rule to endosseous dental implants and dental implant abutments	V2	under revision

Legend Status: worked on /voting process /superseded /under revision /obsolete