

ATTACHMENT 2 to FIAB LETTER

"Extension of the MDR 2017/745 transitional period – confirmation of validity of FIAB MDD 93/42/EEC Certificates"

List of FIAB medical devices for which the extension of the MDR transitional period applies

Medical devices group description	MDD 93/42/EEC CE certificate(s)	expiry	MDR certification agreement with Notified Body 2797 (BSI)
Esophageal Leads Esophageal leads for transesophageal electrophysiology studies and cardioversion	CE 01906 Annex II.3	10/05/2023	Contract Q594293 (28/10/2021) amended by Contract Q682089 (05/10/2022)
External cardiac stimulator "Easypace" single chamber	CE 01906 Annex II.3	10/05/2023	Contract Q720115 (14/03/2023)
External temporary pacemaker – dual chamber (model "1797")	CE 01906 Annex II.3	10/05/2023	Contract Q594293 (28/10/2021) amended by Contract Q682089 (05/10/2022)
Single chamber external temporary pacemaker "1748"	CE 01906 Annex II.3	10/05/2023	Contract Q720115 (14/03/2023)
Sterile single use electrosurgical electrodes Sterile single use electrosurgical pencils Reusable extensions for electrosurgery Reusable electrodes for electrosurgery Sterile single use electrosurgical kits- Reusable electrosurgical pencils	CE 01906 Annex II.3	10/05/2023	Contract Q594293 (28/10/2021) amended by Contract Q624346 (16/02/2022)
Sterile single use tips for reusable cauteries Sterile single use electrocauteries Reusable electrocauteries	CE 01906 Annex II.3	10/05/2023	Contract Q594293 (28/10/2021) Amended by Contract Q640589 (24/05/2022)
Sterile single use epicardial wires "Myopace" (mono and bipolar, quadripolar)	CE 01906 Annex II.3 CE 649635 Annex II.4	10/05/2023 26/05/2024	Contract Q594293 (28/10/2021) amended by Contract Q682089 (05/10/2022)
Rostock Filter	CE 01906 Annex II.3	10/05/2023	Contract Q720115 (14/03/2023)
Nerve stimulator "Neuropacer" single use, sterile	CE 01906 Annex II.3	10/05/2023	Contract Q720115 (14/03/2023)
Needles for EMG and EEG, single use Needles for EMG and EEG, reusable	CE 01906 Annex II.3	10/05/2023	Contract Q720115 (14/03/2023)
Esophageal temperature monitor Connection cable for esophageal temperature monitor and probe Esophageal temperature probe	CE 01906 Annex II.3	10/05/2023	Contract Q594293 (28/10/2021) amended by Contract Q624346 (16/02/2022)
Single use electrosurgical neutral electrodes, single section Single use electrosurgical neutral electrodes, dual section Reusable electrosurgical neutral electrodes	CE 01906 Annex II.3	10/05/2023	Contract Q594293 (28/10/2021)
Temporary cardiac pacing leads "Spike" – bipolar, tripolar, tetrapolar, multipolar	CE 01906 Annex II.3 CE 649635 Annex II.4	10/05/2023 26/05/2024	Contract Q594293 (28/10/2021) amended by Contract Q682089 (05/10/2022)
Sterile lead introducer set peel-away Sterile hemostasis valve introducer kit	CE 01906 Annex II.3	10/05/2023	Contract Q594293 (28/10/2021)
"Extra Safe" dilator sheaths	CE 01906 Annex II.3 CE 720326 Annex II.4	10/05/2023 26/05/2024	Contract Q594293 (28/10/2021) amended by Contract Q682089 (05/10/2022)