

EU Declaration of Conformity

Manufacturer: Vitrex Medical A/S
Vasekaer 6-8
2730 Herlev
Denmark

SRN (Single Registration Number): DK-MF-000024596


Classification: Class A, according to annex VIII (EU) IVDR 2017/746, rule 5.

Conformity assessment route: EU declaration of conformity according to annex II and III of the Regulation (EU) 2017/746 on *in vitro* medical devices.

We hereby declare that the medical device(s) specified in the attached list meet the provisions of the Regulation (EU) 2017/746 on *in vitro* medical devices.

This EU declaration of conformity is issued under the sole responsibility of Vitrex Medical A/S.

Signature:



Peter Jørgensen
Quality and System Manager

Place and date of Issue

Herlev, September 7, 2022

Marlen REF	Vitrex ART.	Bezeichnung	Basic UDI-DI
2920117	125846	RMP 200 ul Länge 125 mm n.hep. Sup.	5706860IC120PP
2920109	126246	RMP 10 ul Länge 125 mm n.hep. Sup.	5706860IC120PP
2920110	126446	RMP 20 ul Länge 125 mm n.hep. Sup.	5706860IC120PP
2920115	127046	RMP 50 ul Länge 125 mm n.hep. Sup.	5706860IC120PP
2920116	127246	RMP 100 ul Länge 125 mm n.hep. Sup.	5706860IC120PP
2920107	128846	RMP 1+2+3+4+5 ul Länge 125 mm n.hep. Sup.	5706860IC120PP
2900000	160246	MHK n.hep. 75x1,1-1,2 mm ID 75 ul Sup.	5706860IC100PH
2900001	160446	MHK n.hep. 75x0,9-1,0 mm ID 60 ul Sup.	5706860IC100PH
2902000	160846	MHK Ammonium-hep. 75x1,1-1,2 mm ID 75 ul Sup.	5706860IC100PH
2901000	161346	MHK hep. 75x1,1-1,2 mm ID 75 ul Sup.	5706860IC100PH
2901001	161546	MHK hep. 75x0,9-1,0 mm ID 60 ul Sup.	5706860IC100PH
2901002	162746	MHK hep. 75x0,5-0,6 mm ID 18 ul Sup.	5706860IC100PH
2900999396	163246	MHK n.hep. 75x1,1-1,2 mm ID 75 ul Sup. Bulk	5706860IC101PK
2901999396	163646	MHK hep. 75x1,1-1,2 mm ID 75 ul Sup. Bulk	5706860IC101PK
290900091	164246	MHK EDTA 3,3 mg/ml 75x1,1-1,2 mm ID 75 ul Sup.	5706860IC100PH
2909000	167346	MHK EDTA 1,65 mg/ml 75x1,1-1,2 mm ID 75 ul Sup.	5706860IC100PH
2910109	174346	Mikropip end-to-end 10 ul n.hep. Länge 29 mm Sup.	5706860IC111PN
2910110	174546	Mikropip end-to-end 20 ul n.hep. Länge 29 mm Sup.	5706860IC111PN
2911109	177146	Mikropip end-to-end 10 ul hep. Länge 29 mm Sup.	5706860IC111PN
2911110	177246	Mikropip end-to-end 20 ul hep. Länge 29 mm Sup.	5706860IC111PN
2951303	181446	Blutgaskapillaren 75x1,75 mm 82,5 ul hep. Sup.	5706860IC130PS
2951302	182346	Blutgaskapillaren 125x2,3 mm 220 ul hep. Sup.	5706860IC130PS
2951301	182446	Blutgaskapillaren 100x2,3 mm 175 ul hep. Sup.	5706860IC130PS
2951300	182546	Blutgaskapillaren 75x2,3 mm 130 ul hep. Sup.	5706860IC130PS
2953301	183346	Blutgaskap 100x2,35 mm 175 ul Lithium-hep. Sup.	5706860IC130PS
2951305	187646	Blutgaskapillaren 125x1,75 mm 137,5 ul hep. Sup.	5706860IC130PS
2920114	126846	RMP 44,7 ul Länge 125 mm n.hep. Sup.	5706860IC120PP