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 conformity declaration 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
PRRC

Place and date of Issue

Herlev, May 12, 2025

Vitrex Medical a/s
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Item no.	Description		Basic UDI-DI
105113	CAP.TUBE 0.42x0.60x80mm	10x500pcs	5706860IC181QB
117513	PIP 50 Li Orange	3mm ORANGE AROUND MIDDLE	5706860IC111PN
118913	PIP 3 EDTA		5706860IC111PN
120013	SEDICAPS		5706860IC120PP
124713	PRECAL 25µl K2EDTA VITREX		5706860IC120PP
124813	PRECAL 50-100µl K2EDTA VITREX		5706860IC120PP
125513	PRECAL 5-10ul VITREX		5706860IC120PP
125613	PRECAL 20-50ul VITREX		5706860IC120PP
125713	PRECAL 50-100ul VITREX		5706860IC120PP
125913	PRECAL 20-40ul VITREX		5706860IC120PP
126013	PRECAL 5ul VITREX		5706860IC120PP
126113	PRECAL 10 ul K2EDTA VITREX		5706860IC120PP
126213	PRECAL 10ul VITREX		5706860IC120PP
126413	PRECAL 20ul VITREX		5706860IC120PP
126613	PRECAL 25ul VITREX		5706860IC120PP
126913	PRECAL 200ulK2EDTA VITREX		5706860IC120PP
127013	PRECAL 50ul VITREX		5706860IC120PP
127113	PRECAL 50-100ul Na VITREX		5706860IC120PP
127213	PRECAL 100ul VITREX		5706860IC120PP
127313	PRECAL 20ul K2EDTA VITREX		5706860IC120PP
127713	PRECAL 100-200 Na VITREX		5706860IC120PP
127813	PRECAL 20ul Na VITREX		5706860IC120PP
128113	PRECAL 200ulK2EDTA VITREX	100pcs/Vial	5706860IC120PP
128213	PRECAL 44,7ul Na VITREX		5706860IC120PP
128613	PRECAL 100ul Na VITREX		5706860IC120PP
128813	PRECAL 1-5 ul VITREX		5706860IC120PP
128913	PRECAL 1-5ul Na VITREX		5706860IC120PP
129013	PRECAL 50ul K2EDTA VITREX		5706860IC120PP
129213	PRECAL 100ulK2EDTA VITREX		5706860IC120PP
129313	PRECAL 40ul VITREX		5706860IC120PP
129413	PRECAL 100-200ul VITREX	125 pcs	5706860IC120PP
140013	WAX PLATE VITREX	BOX OF 10 PCS	5706860IC1901HY
140014	WAX PLATE VITREX (F)	BOX OF 10 PCS	5706860IC1901HY
140313	PIPETTE HOLDER	BOX OF 100	5706860IC1902J2
140413	PIPETTE HOLDER VI-3	BOX OF 100 SIPHON WHITE	5706860IC1902J2
140513	PIPETTE STOPPER VI-4	BOX OF 1000 VITREX	5706860IC1902J2
140613	PIPETTE STOPPER VI-4 10x100	10 X 100 stk	5706860IC1902J2
140713	END-CAP FOR OD 1.50-2.20	BOX OF 500PCS	5706860IC1903J4
140813	END CAP FOR OD 2.20-2.80	BOX OF 500 VITREX	5706860IC1903J4
140913	STIRRER 1,0x9mm 250pcs/vial		5706860IC1904J6
141013	STIRRER 0,6x9mm 250 pcs		5706860IC1904J6
142113	STIRRER 0.8x9mm 250 pcs		5706860IC1904J6

154313	BLOOD-GAS 140 µL NA-HEP		5706860IC130PS
155013	CAP.TUBE	0.77X1.55X75mm	5706860IC100PH
155113	CAP.TUBE EDTA 3,30mg/ml	0.77X1.55X75mm	5706860IC100PH
155313	CAP.TUBE 35µl Li	0.77X1.55X75mm	5706860IC100PH
160213	HEMATOCRIT BRIS	VITREX LABEL	5706860IC100PH
160214	HEMATOCRIT BRIS (F)	VITREX LABEL	5706860IC100PH
160313	HEMATOCRIT BSRI VITREX		5706860IC100PH
160413	HEMATOCRIT BSRS		5706860IC100PH
160513	HEMATOCRIT BCRS		5706860IC100PH
160613	HEMATOCRIT LSRS		5706860IC100PH
160813	HEMATOCRIT ARIS (ENG VIT)		5706860IC100PH
161113	HEMATOCRIT PLRI	ENG VITREX	5706860IC100PH
161313	HEMATOCRIT NRIS Na-Hep	VITREX LABEL	5706860IC100PH
161314	HEMATOCRIT NRIS Na-Hep (F)	VITREX LABEL	5706860IC100PH
161513	HEMATOCRIT NSRS		5706860IC100PH
161613	HEMATOCRIT NCRS		5706860IC100PH
161813	HEMATOCRIT LRIS		5706860IC100PH
162313	HEMATOCRIT K2 EDTA PRECAL	1,02 x 1,50 x 75 mm K2 EDTA	5706860IC100PH
162713	HEMATOCRIT PNTI		5706860IC100PH
163213	HEMATOCRIT BRIS/E		5706860IC101PK
163413	HEMATOCRIT BSRS/E		5706860IC101PK
163613	HEMATOCRIT NRIS/E		5706860IC101PK
164113	HEMATOCRIT EDTA	Markering 32 & 64	5706860IC100PH
164213	HEMATOCRIT EDTA VITREX	DOBBELT EDTA 3.3mg/ml	5706860IC100PH
165013	PIP 1P	1 ul Vitrex end-to-end plain (dark blue)	5706860IC111PN
165113	PIP 2P	2 ul Vitrex end-to-end plain (red)	5706860IC111PN
165213	PIP 3PK	3 ul Vitrex end-to-end plain (yellow)	5706860IC111PN
165313	PIP 4P	4 ul Vitrex end-to-end plain (green)	5706860IC111PN
165413	PIP 5PK	5 ul Vitrex end-to-end plain (white)	5706860IC111PN
165513	PIP 10P		5706860IC110PL
165613	PIP 20P		5706860IC110PL
165713	PIP 25P		5706860IC110PL
165913	PIP 50P		5706860IC110PL
166013	PIP 100P		5706860IC110PL
167313	HEMATOCRIT K2 EDTA		5706860IC100PH
167713	PIP 3NK		5706860IC111PN
167913	PIP 5NK		5706860IC111PN
168513	PIP 100N		5706860IC110PL
169513	PIP 10A		5706860IC110PL
170113	PIP 5 EDTA	0,46 x 1,25 x 29 mm	5706860IC111PN
171113	PIP 50UL K2EDTA 50PCS	end-to-end	5706860IC111PN
172213	PIP 8µl 16mm UD.1,50mm		5706860IC111PN
172613	PIP 8µL 24mm 45 pr vial	(10x45pcs)x22=9900/CASE	5706860IC111PN

173313	PIP 8µL EDTA 24mm	3,30mg/ml EDTA 100pcs/via	5706860IC111PN
174113	PIP 10 K2EDTA VITREX		5706860IC111PN
174313	PIP 10PK	10 ul Vitrex end-to-end plain (orange)	5706860IC111PN
174413	PIP 20 K2EDTA	Vitrex Micro Pipettes	5706860IC111PN
174513	PIP 20PK	20 ul Vitrex end-to-end plain (black)	5706860IC111PN
174613	PIP 25PK	1,05x13,5x29 mm	5706860IC111PN
174813	PIP 40PK		5706860IC111PN
174913	PIP 50PK 50PCS		5706860IC111PN
175113	PIP 40µl K2EDTA	CS 10100-03-5	5706860IC111PN
175413	PIP 20 K2EDTA + Purple		5706860IC111PN
177113	PIP 10NK		5706860IC111PN
177213	PIP 20NK		5706860IC111PN
177313	PIP 25NK	VITREX	5706860IC111PN
177413	PIP 40NK		5706860IC111PN
177513	PIP 50NK 50PCS		5706860IC111PN
177613	PIP 0.5PK		5706860IC111PN
177713	PIP 44.7NK 50PCS		5706860IC111PN
178213	PIP 25 EDTA VITREX	end-to-end	5706860IC111PN
178313	PIP 100ul K2EDTA	CS 12314-03-5	5706860IC110PL
179413	PIP 25AK	VITREX	5706860IC111PN
179513	PIP 40AK VITREX	end-to-end	5706860IC111PN
181713	BLOOD GAS 125MM 220ul EDTA	EDTA	5706860IC130PS
182013	BLOOD GAS 125MM 220ul	lithium heparin	5706860IC130PS
182313	BLOOD GAS 125MM 220ul		5706860IC130PS
182413	BLOOD GAS 100MM 175ul		5706860IC130PS
182513	BLOOD-GAS 75MM, 130ul	Na-Heparin	5706860IC130PS
182613	BLOOD-GAS 75MM, 130ul	lithium heparin	5706860IC130PS
182621	BLOOD-GAS 75MM, 130ul	lithium heparin	5706860IC130PS
183213	BLOOD GAS 100MM 175ul 2.5	lithium heparin	5706860IC130PS
183313	BLOOD GAS 100mm 175ul	Li hep. 80IU/ml	5706860IC130PS
183321	BLOOD GAS 100mm 175ul	Li hep. 80IU/ml	5706860IC130PS
185013	CAP.TUBE 1,1 X 1.65 X 100mm	Li hep. 240IU/ml	5706860IC181QB
210013	CAP.TUBE 0.80x1.00 x 80mm	2000 pcs	5706860IC181QB
210113	CAP.TUBE 0.80x1.00 x100mm	2000 pcs	5706860IC181QB
210213	CAP.TUBE 0.90x1.20 x 70mm	1000 pcs	5706860IC181QB
210313	CAP.TUBE 0.90x1.20 x100mm	1000 pcs	5706860IC181QB
210413	CAP.TUBE 1.00x1.40 x 75mm	1000 pcs	5706860IC181QB
210513	CAP.TUBE 1.00x1.40 x 80mm	1000 pcs	5706860IC181QB
210613	CAP.TUBE 1.00x1.40 x100mm	1000 pcs	5706860IC181QB
210713	CAP.TUBE 1.00x1.40 x125mm	1000 pcs	5706860IC181QB
210813	CAP.TUBE 1.00x1.40 x150mm		5706860IC181QB
210913	CAP.TUBE 1.00x1.40 x200mm	5000 pcs	5706860IC181QB
211013	CAP.TUBE 1.15x1.55 x 80mm	1000 pcs	5706860IC181QB

211113	CAP.TUBE 1.15x1.55 x100mm	1000 pcs	5706860IC181QB
211213	CAP.TUBE 1.20x1.65 x 75mm	500 pcs	5706860IC181QB
211313	CAP.TUBE 1.20x1.65 x100mm	500 pcs	5706860IC181QB
211413	CAP.TUBE 1.20x1.65 x125mm	1000 pcs	5706860IC181QB
211513	CAP.TUBE 1,20x1,65 x150mm	1000 pcs	5706860IC181QB
211613	CAP.TUBE 1.20x1.65 x200mm	3000 pcs	5706860IC181QB
211713	CAP.TUBE 1.40x1.90 x125mm	500 pcs	5706860IC181QB
212113	CAP.TUBE 1,55x2,35.x67,4mm	400 pcs	5706860IC181QB
213013	CAP.TUBE 0.80x1.00 x 80mm	100 pcs	5706860IC181QB
213113	CAP.TUBE 0.80x1.00 x100mm	100 pcs	5706860IC181QB
213213	CAP.TUBE 0.90x1.20 x 70mm	100 pcs	5706860IC181QB
213413	CAP.TUBE 1.00x1.40 x 75mm	10x100 pcs	5706860IC181QB
213513	CAP.TUBE 1.00x1.40 x 80mm	100 pcs	5706860IC181QB
213613	CAP.TUBE 1.00x1.40 x100mm	100 pcs	5706860IC181QB
213713	CAP.TUBE 1.00x1.40 x125mm	100 pcs	5706860IC181QB
213813	CAP.TUBE 1.00x1.40 x150mm	100 pcs	5706860IC181QB
213913	CAP.TUBE 1.00x1.40 x200mm	100 pcs	5706860IC181QB
214113	CAP.TUBE 1.15x1.55 x100mm	100 pcs	5706860IC181QB
214313	CAP.TUBE 1.20x1.65 x100mm	100 pcs	5706860IC181QB
214513	CAP:TUBE 1.20x1.65 x150mm	100pcs	5706860IC181QB
214913	CAP.TUBE 1.50x2.00 x100mm	50 pcs	5706860IC181QB
221913	CAP.TUBE Na 1.5x2.0x100mm	500 pcs	5706860IC181QB
224513	CAP.TUBE 1.20x1.65 x150mm	100pcs Na	5706860IC181QB
252013	CAP.TUBE Na PLASTIC	100 pcs 0,93x1,75x100mm	5706860IC131PU
260213	HEMATOCRIT PLAIN PLASTIC	BLUE	5706860IC102PM
261313	HEMATOCRIT NA-HEP PLASTIC	RØD	5706860IC102PM
267213	HEMATOCRIT PLAIN/E PLASTIC	BULK 1000 PCS/BOX	5706860IC102PM
282013	Plastic Blood Gas Tubes Li 220µl 200pcs		5706860IC131PU
282313	Plastic Blood Gas Tubes Na 220µl 200pcs		5706860IC131PU
282413	Plastic Blood Gas Tubes Na 175µl 200pcs		5706860IC131PU
282513	Plastic Blood Gas Tubes Na 130µl 200pcs		5706860IC131PU
282613	Plastic Blood Gas Tubes Li 130µl 200pcs		5706860IC131PU