

Declaration of Conformity

We, MTP Medical Technologies GmbH herewith declare under our sole responsibility according to Annex II (excl. 4.) of Council Directive MDD 93/42/EEC concerning medical devices conformity of following products with this directive:

Dialyzer VitaPES®

Class IIb medical devices,
GMDN Code 47072: Hollow fibre haemodialysis dialyser, high flux, single use)

MTP Medical Technologies GmbH operates under a quality management system in accordance with EN ISO 13485:2016 and MDD 93/42.

This declaration is valid for below-mentioned products according to Technical Documentation (Device Master Record Dialyzer PAD-0) with revision status of respective product release date.

Trade Name	Article REF No.	Article order code	Trade Name	Article REF No.	Article order code
VitaPES® 150 HF	7 01 04 215	7215	VitaPES® 150 LX	7 01 11 315	7315
VitaPES® 170 HF	7 01 08 217	7217	VitaPES® 170 LX	7 01 11 317	7317
VitaPES® 190 HF	7 01 05 219	7219	VitaPES® 190 LX	7 01 11 319	7319
VitaPES® 210 HF	7 01 06 221	7221	VitaPES® 210 LX	7 01 11 321	7321
VitaPES® 140 BF	7 01 10 414	7414	VitaPES® XPS 18 L	7551	7551
VitaPES® 160 BF	7 01 10 416	7416	VitaPES® XPS 19 L	7552	7552
VitaPES® 180 BF	7 01 10 418	7418	VitaPES® XPS 20 L	7553	7553
VitaPES® 200 BF	7 01 10 420	7420	VitaPES® XPS 22 L	7555	7555
VitaPES® LF 18 Plus	7 01 15 818	7818	VitaPES® XPS 18 H	7651	7651
VitaPES® LF 19 Plus	7 01 15 819	7819	VitaPES® XPS 19 H	7652	7652
VitaPES® LF 20 Plus	7 01 15 820	7820	VitaPES® XPS 20 H	7653	7653
VitaPES® LF 22 Plus	7 01 15 822	7822	VitaPES® XPS 22 H	7655	7655
VitaPES® DN 18 HF	7 01 14 228	7228			

The Technical Documentation is in conformity with essential requirements of MDD 93/42 and other applicable standards and guidelines. The Technical Documentation is recorded and kept by R&D manager of MTP.

This declaration replaces declaration dated 2016-06-01 and is valid until 2023-10-08.

Name and address of notified body:

MDC medical device certification GmbH, Kriegerstr. 6, 70191 Stuttgart,
Identification number 0483

Name and address of manufacturer:

MTP Medical Technologies GmbH, Kunstseidenstraße 4, 01796 Pirna, Germany

Pirna, 2018-10-09


Gudrun Hausbrand
CEO, Plant Manager


Dr. Konrad Martins
CEO, QM Representative