pfmmedical

Konformitätserklärung
Declaration of conformity

Hersteller / Manufacturer:	pfm medical cpp S.A. Allée du Quartz 9, 2300 La Chaux-de-Fonds Switzerland

Wir erklären in alleiniger Verantwortung, dass
We declare under our sole responsibility that

das Medizinprodukt **the medical device**	Implantable Vascular Access Ports and Accessories

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REF: List of codes in page 2

UMDNS Bezeichnung, (UMDNS Code) **UMDNS description, (UMDNS Code)**	Infusion/Injection Port, implantable (16854)
GMDNS description, (GMDN Code)	Infusion/Injection Port, implantable (35911)
Risikoklasse / Risk Class; Regel / Rule gem./acc. to MDD 93/42/EEC, Annex IX	III, 8

die Anforderungen der RL für Medizinprodukte 93/42/EWG u. der Ergänzungs-RL 2007/47/EG erfüllt.
meets the requirements of the MDD 93/42/EEC as amended by Directive 2007/47/EC.

Konformitätsbewertungsverfahren **Conformity assessment procedure**	gemäß der RL 93/42/EWG acc. to MDD 93/42/EEC
Anhang / Annex	II
Konformitätsbewertungsstelle **Notified Body** **Kennnummer / Identification Number**	DEKRA Certification GmbH Stuttgart Handwerkstrasse 15, 70565 Stuttgart 0124
Zertifikat Nr. / Certificate No.	EC Design Examination Certificate 51502-23-A0 EC Quality Assurance Certificate 51502-16-00
Datum / Date: **Gültig bis / Expiry date:**	08 January 2021 21 March 2024

Unterschrift / Signature:



Betty RÜFER
Quality & Regulatory Manager

Implantable Vascular Access Ports and Accessories

Port body family	Catheter	French size	Article number	Contrast / Non-Contrast
Jet Port Plus	PUR100160	F4.8	61.635.35.075	*Non-Contrast*
Jet Port Plus	PUR130220-F	F6.6	61.635.33.075	*Non-Contrast*
Jet Port Plus	SIL 100220	F6.6	61.645.35.075	*Non-Contrast*
Jet Port Plus	PUR160260-F	F8	61.635.32.080	*Non-Contrast*
Jet Port Plus	SIL 160280	F8.4	61.645.31.080	*Non-Contrast*
Jet Port Plus II	PUR130220-F	F6.6	61.635.73.077	*Contrast*
Jet Port Plus II	PUR160260-F	F8	61.635.72.087	*Contrast*
Jet Port Plus Low Profile	PUR100160	F4.8	61.635.07.070	*Non-Contrast*
Jet Port Plus Low Profile	PUR130220-F	F6.6	61.635.03.070	*Non-Contrast*
Jet Port Plus Low Profile	SIL 100220	F6.6	61.647.07.070	*Non-Contrast*
Tita Jet Light	PUR100160	F4.8	61.635.25.075	*Non-Contrast*
Tita Jet Light	PUR130220-F	F6.6	61.635.23.075	*Non-Contrast*
Tita Jet Light	SIL 100220	F6.6	61.645.25.075	*Non-Contrast*
Tita Jet Light	PUR160260-F	F8	61.635.22.080	*Non-Contrast*
Tita Jet Light	SIL 160280	F8.4	61.645.21.080	*Non-Contrast*
Tita Jet Light II	PUR130220-F	F4.8	61.635.83.077	*Contrast*
Tita Jet Light II	PUR160260-F	F6.6	61.635.82.087	*Contrast*
Tita Jet Light Low Profile	PUR100160	F4.8	61.635.09.077	*Contrast*
Tita Jet Light Low Profile	PUR130220-F	F6.6	61.635.08.077	*Contrast*
T-Port	PUR100160	F4.8	61.635.55.075	*Non-Contrast*
T-Port	PUR130220-F	F6.6	61.635.53.075	*Non-Contrast*
T-Port	PUR130220-F	F6.6	61.635.53.077	*Contrast*
T-Port	SIL 100220	F6.6	61.645.55.075	*Non-Contrast*
T-Port	PUR160260-F	F8	61.635.52.080	*Non-Contrast*
T-Port	PUR160260-F	F8	61.635.52.087	*Contrast*
T-Port	SIL 160280	F8.4	61.645.51.080	*Non-Contrast*
T-Port Low Profile	PUR100160	F4.8	61.635.65.075	*Non-Contrast*
T-Port Low Profile	PUR130220-F	F6.6	61.635.63.075	*Non-Contrast*
T-Port Low Profile	PUR130220-F	F6.6	61.635.63.077	*Contrast*
T-Port Low Profile	SIL 100220	F6.6	61.645.65.075	*Non-Contrast*
T-Port Low Profile	PUR160260-F	F8	61.635.62.087	*Contrast*