

PRÄMETA GmbH & Co. KG
Genker Strasse 16
53842 Troisdorf

Declaration of conformity

according to appendix VII of Council Directive 93/42/EEG relating to medical devices

name

Aqua-Protect AP

article number

950-AP 17

950-AP 21

950-AP 26

950-AP 31

Aqua-Protect LP

950-LP 20

950-LP 25

950-LP 33

950-LP 44

Medical devices, class I, according to directive 93/42/EEG annex IX

Applied norms

<u>norm</u>	<u>number</u>	<u>name</u>	<u>date</u>
DIN EN ISO	9001	Quality management systems	2015-11
DIN EN ISO	13485	Medical devices quality management system	2016-03
DIN EN ISO	10993	Testing of biocompatibility and cytotoxicity, part1	2010-04
DIN EN ISO	14971	Risk management and risk analysis for medical devices	2013-04
MPG		Medizinproduktegesetz (german)	2015-08
MDD	93/42/EEC	Medical devices	2007-10
DIN EN ISO	15223	Symbols for medical devices	2013-02
DIN EN	1041	Information supplied by the manufacturer of medical devices	2013-12
DIN	58946	Sterilization - Steam sterilizers - Part 7	2014-01

We declare in our sole responsibility that the above described products meet the requirements of the Directive 92/42/EEG and of the German Law on Medical Products (MPG).

The products are labelled with a CE-mark.



7.4.16



date / signature