

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

<u>name</u>	<u>article number</u>	<u>name</u>	<u>article number</u>
Grey Tourniquet	901	Spare tape	901-1
Green Tourniquet	902	Spare tape	902-2
Easy Tourniquet	904	Spare tape	902-3
Tourniquet PW	906	Spare tape	904-4
Emergency Tourniquet	910 A	Spare tape	910-10
Pressure bridge	910-20		

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.



18.5.16 

date / signature