Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 039219 0033 Rev. 00

Manufacturer:
Proxomed Medizintechnik GmbH
Daimlerstr. 6
63755 Alzenau
GERMANY

Facility(ies):
Proxomed Medizintechnik GmbH
Daimlerstr. 6, 63755 Alzenau, GERMANY

Product Category(ies):
Medical Training Devices with Pulse and Force Measuring Function for Use in Cardiology, Neurology, Orthopaedics and Traumatology

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: 713166017

Valid from: 2019-12-09
Valid until: 2024-05-26

Date, 2019-12-09

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany