



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 18 05 24995 017

Manufacturer:

ELCAT GmbH

Bgm.-Finsterwalder-Ring 27
82515 Wolfratshausen
GERMANY



Facility(ies):

ELCAT GmbH
Bgm.-Finsterwalder-Ring 27, 82515 Wolfratshausen, GERMANY

Product Category(ies):

**Plethysmography Devices,
Ultrasound-Doppler-Systems,
Control- and Evaluation Software
for Ultra Sound-Doppler-Systems
and Plethysmography Devices**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

713132849

Valid from:

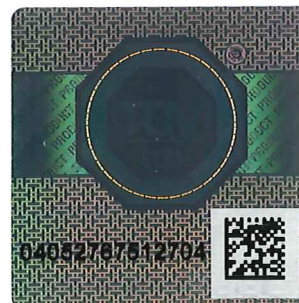
2018-07-02

Valid until:

2023-07-01

Date, 2018-05-14

Stefan Preiß



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

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