ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 16 03 23782 082

Manufacturer:

GE Vingmed Ultrasound A/S
Strandpromenaden 45
3191 Horten
NORWAY

Facility(ies):

GE Vingmed Ultrasound A/S
Strandpromenaden 45, 3191 Horten, NORWAY

Product Category(ies):

Diagnostic Ultrasound Systems, related Ultrasound Probes and Standalone Software for Ultrasound-Image Processing

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.: 713080867

Valid from: 2016-09-02
Valid until: 2021-09-01

Date, 2016-06-09

Stefan Preiß

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

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