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

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

GE Healthcare

DECLARATION OF CONFORMITY

Following the provisions of the medical devices directive 93/42/EEC, Annex II and of the directive 2011/65/EU and directive 2014/53/EU, Annex II

We

Manufacturer

GE Vingmed Ultrasound AS

Strandpromenaden 45

3191 Horten, Norway

Declare under our sole responsibility that the device:

Vscan Extend

Ultrasound System, Imaging, General-Purpose

Ref: see addendum

GMDN Code: **40761**

Classification rule (93/42/EEC Annex IX) **10** Class: IIa

To which this declaration relates, is in conformity with the requirements of the medical devices directive 93/42/EEC which apply to it and with the requirements of the directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment and Directive 2014/53/EU.

This conformity is based on the following elements:

- For the directive 93/42/EEC (MDD)
  - Technical Documentation/DHF Ref./ réf: DOC1929366, of the product to which this declaration relates
  - EC certificate: approval of full quality assurance system (Annex II of the directive 93/42 EEC) delivered by TÜV SÜD Product Service GmbH, Ridlerstrasse 65, 80339 Munich, Germany (Notified Body 0123) / Certificate N G1 16 03 23782 082
  - harmonized standards applied on the product to which this declaration relates

Standard	Description
EN 60601-1:2006/A1:2013	Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance
EN 60601-2-37:2008	Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.

Horten, Norway, 13-April-2018

Charlotte K. M. Jørgensen
Senior Regulatory Affairs Leader, U/S

This EC declaration of conformity supersedes the previous declaration dated 21-March-2018

Reference of the Declaration: DOC1929370

Standard	Description
EN 60601-1-2:2007/AC2010	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 62366:2008	Medical devices - Application of usability engineering to medical devices
EN 62304:2006/AC:2008	Medical device software - Software life-cycle processes
EN ISO 10993-1:2009/AC:2010	Biological evaluation of medical devices
EN ISO 15223-1:2016	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)
EN1041:2008	Information supplied by the manufacturer with medical devices
EN 60601-1-11:2010	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
EN 1789:2007+A1:2010	Medical vehicles and their equipment - Road ambulances
EN 13718-1:2008	Medical vehicles and their equipment - Air ambulances - Part 1: Requirements for medical devices used in air ambulances

- For the directive 2011/65/EU (RoHS)
  - Technical Documentation/DHF Ref./ réf: DOC1929366 of the product to which this declaration relates
- For the directive 2014/53/EU
  - Technical Documentation/DHF Ref./ réf: DOC1929366 of the product to which this declaration relates
  - Harmonized standards applied on the product to which this declaration relates

ETSI EN 301 489-1 V2.2.0	Electro Magnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonized Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU
ETSI EN 301 489-17 V3.2.0	Electro Magnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonized Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU
ETSI EN 300 328 V2.1.1	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU

Horten, Norway, 13-April-2018

Charlotte K. M. Jørgensen
Senior Regulatory Affairs Leader, U/S

ADDENDUM TO THE DECLARATION OF CONFORMITY DOC1929370

Vscan Extend – Accessories and Components

Console Name	GE Part No	
	R1	R2
Vscan Extend (Vscan Extend Dual USB)	5693455 5476840	
Vscan Extend (Vscan Extend Sector USB)	5693455 5641368	
Components	**GE Part No**	
AC/DC adapter [1]	5693487	
Battery [1]	5693456	
Micro SD card	GM200047	
USB cable	GM200049	
Soft Case	5737513	
External Battery Charger	5716861	
Sector Probe (phased array transducer G3S)	5641368	
Dual Probe (phased array transducer G3S and Linear Array transducer G8L)	5476840	
Accessories	**GE Part No**	
	R1	R2
Gel [1]	098B2004	
Robust Case	5737511 5737512	
SW Options [2]	**GE Part No**	
	R1	R2
USB to Wi-Fi Access	5732131 5732132	
Wi-Fi Access to DICOM	5737618	
USB to DICOM	5732132 5732131 5737618	
	R1	R2
R1 to R2 update	5793418	NA
LVivo EF	NA	5792751

[1] Components and Accessories may carry the CE mark and, when applicable, the Notified Body number corresponding to the EC Declaration under which the products are CE marked by their manufacturer.
[2] Vscan Extend exports images, videos and exams to Tricefy (a separate cloud-based case-exchange solution provided by Trice Imaging) through "Tricefy Uplink" Application installed on the device which is provided and registered by Trice Imaging as part of the Tricefy device.

GE Vingmed Ultrasound AS has verified the mutual compatibility of the components, accessories and software options in combination with the Vscan Extend and included relevant information to the users with the Vscan Extend instructions for use. Capabilities also include access to GE Marketplace, which shall allow the user to download GE approved software applications to the device.

Horten, Norway, 13-April-2018

Charlotte K. M. Jørgensen
Senior Regulatory Affairs Leader, U/S

Reference of the Declaration: DOC1929370