Electronic Signature Information

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DOC2506507_Vscan Air CL EC DoC_28Feb2021_signed.pdf	DOC2506507_Vscan Air CL EC DoC_28Feb2021_signed	81342
DOC2506507_Vscan Air CL EC DoC_Template_28Feb2021.docx	DOC2506507_Vscan Air CL EC DoC_Template_28Feb2021	3236368

Route	Signer	Function	Status	Comments	Completion Date
R-10028260	305022609_liwen__wei		Approve	I hereby confirm that the document is signed by me	27 Feb 2021 23:48:19 GMT

Periodic Review

There are no signatures or routes related to this business object.

Obsolesence Approval

There are no signatures or routes related to this business object.

* Printed versions are For Reference Only *
+ Indicates a task was reassigned from an original assignee

Released

GE Healthcare

DECLARATION OF CONFORMITY

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

We

Manufacturer:
GE Vingmed Ultrasound AS
Strandpromenaden 45
3191 Horten, Norway

Manufacturing site:
GE Healthcare Austria GmbH & Co OG
Tiefenbach 15
A-4871 Zipf, Austria

Declare under our sole responsibility that the device:

Vscan Air CL

General ultrasound imaging system, battery-powered.
Software version: **1.1**
Ref.: See attached addendum.
GMDN Code: **60924**
Classification rule (93/42/EC 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 ofthe 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, ref Technical File **DOC2506513**, 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 (Notified Body 0123), Certificate No.: G1 023782 0112, issued on September 02, 2019.
  - 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 + A1:2016	Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.
EN 60601-1-2:2015	Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests

Wuxi, China, 28 February 2021 Wei Liwen, Regulatory Affairs Leader

This EC declaration of conformity is the first declaration for the full production systems of Vscan Air CL

GE Healthcare

Standard	Description
EN 60601-1-6:2010 + A1:2015	Medical electrical equipment, collateral standard
EN 62366-1: 2015	Medical devices - Application of usability engineering to medical devices
EN 62304:2006 + A1:2015	Medical device software - Software life-cycle processes
EN 1041:2008 + A1:2013	Information supplied by the manufacturer with 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)
EN 1789:2007+A2:2014	Medical vehicles and their equipment - Road ambulances
EN 13718-1:2014	Medical vehicles and their equipment - Air ambulances - Part 1: Requirements for medical devices used in air ambulances
EN ISO 10993-1: 2009 / AC:2010	Biological evaluation of medical devices
EN 60601-1-11:2015	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
EN60601-1-12:2015	General requirements for basic safety and essential performance medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment

- For the directive 2011/65/EU (RoHS)
  - Technical documentation, ref Technical File **DOC2506513**, of the product to which this declaration relates.

- For the directive 2014/53/EU (Radio Equipment Directive)
  - Technical documentation, ref Technical File **DOC2506513**, of the product to which this declaration relates.
  - 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
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 301 489-3 V2.1.1	Electro Magnetic Compatibility (EMC) standard for radio equipment and services; Part 3: Specific conditions for Short-Range Devices (SRD) operating on frequencies between 9 kHz and 246 GHz; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/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 EN300 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
ETSI EN301 893 V2.1.1	5 GHz RLAN; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
ETSI EN 300 330 V2.1.0	Short Range Devices (SRD); Radio equipment in the frequency range 9 kHz to 25MHz and inductive loop systems in the frequency range 9 kHz to 30 MHz; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU

Wuxi, China, 28 February 2021 Wei Liwen, Regulatory Affairs Leader

GE Healthcare

This EC declaration of conformity is the first declaration for the full production systems of Vscan Air CL

GE Healthcare

ADDENDUM TO THE EC DECLARATION OF CONFORMITY dated 28 February 2021

PRODUCT Name	GEHC Cat # [1]	Part number[2]	REF[3]
Vscan Air CL	H45611CB	GP000158	Vscan Air CL G1
	H45611AD	GP000153	Vscan Air CL C1

OPTIONS AND ACCESSORIES [4]	GEHC Cat # [1]	Part number[2][5]	REF[3]
Vscan Air	N/A	GP000250	Vscan Air for iOS
	N/A	GP000240	Vscan Air for Android
International AC Adapters	H45611AH	GP200113 GP200114	N/A
Wireless Charger Pad	H45581ZZ/H45611CG	GP200303	N/A
Vscan Air Protective Carrying Case	H45611AG	GP200301	N/A

Notes :

1. GEHC Cat # identifies the device(s) in the manufacturer's catalog and is usually included on commercial documents like sale contract, order processing documents and shipping documents.
2. Part number identifies the device in the manufacturer's design, manufacturing and service documentation.
3. REF is affixed to the devices as product identifier under the harmonized symbol **REF**
4. Options and Accessories are compatible with the Vscan Air CL, and bear the CE-mark and, if applicable, Notified Body number corresponding to the EC Declaration under which it is CE-marked. GE Vingmed Ultrasound AS has verified the mutual compatibility of the device in combination with Vscan Air CL and included relevant information to users with the Vscan Air user manual. This activity was subject to appropriate methods of internal monitoring, verification and validation.
5. The Vscan Air part number GP000250, GP000240 will not be seen on the device

Wuxi, China, 28 February 2021 Wei Liwen, Regulatory Affairs Leader

This EC declaration of conformity is the first declaration for the full production systems of Vscan Air CL

GE Healthcare

DECLARATION OF CONFORMITY

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Wuxi, China, 28 February 2021

Wei Liwen, Regulatory Affairs Leader

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Wei Liwen Regulatory Affairs Leader
28, Feb. 2021

GE Healthcare

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Standard	Description
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ETSI EN 301 489-3 V2.1.1	Electro Magnetic Compatibility (EMC) standard for radio equipment and services; Part 3: Specific conditions for Short-Range Devices (SRD) operating on frequencies between 9 kHz and 246 GHz; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU
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Wuxi, China, 28 February 2021 Wei Liwen, Regulatory Affairs Leader

This EC declaration of conformity is the first declaration for the full production systems of Vscan Air CL

Wei Liwen, Regulatory Affairs Leader

28 Feb. 2021

GE Healthcare

ADDENDUM TO THE EC DECLARATION OF CONFORMITY dated 28 February 2021

PRODUCT Name	GEHC Cat # [1]	Part number[2]	REF[3]
Vscan Air CL	H45611CB	GP000158	Vscan Air CL G1
	H45611AD	GP000153	Vscan Air CL C1

OPTIONS AND ACCESSORIES [4]	GEHC Cat # [1]	Part number[2][5]	REF[3]
Vscan Air	N/A	GP000250	Vscan Air for iOS
	N/A	GP000240	Vscan Air for Android
International AC Adapters	H45611AH	GP200113 GP200114	N/A
Wireless Charger Pad	H45581ZZ/H45611CG	GP200303	N/A
Vscan Air Protective Carrying Case	H45611AG	GP200301	N/A

Notes :

1. GEHC Cat # identifies the device(s) in the manufacturer's catalog and is usually included on commercial documents like sale contract, order processing documents and shipping documents.
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3. REF is affixed to the devices as product identifier under the harmonized symbol REF
4. Options and Accessories are compatible with the Vscan Air CL, and bear the CE-mark and, if applicable, Notified Body number corresponding to the EC Declaration under which it is CE-marked. GE Vingmed Ultrasound AS has verified the mutual compatibility of the device in combination with Vscan Air CL and included relevant information to users with the Vscan Air user manual. This activity was subject to appropriate methods of internal monitoring, verification and validation.
5. The Vscan Air part number GP000250, GP000240 will not be seen on the device

Wuxi, China, 28 February 2021

Wei Liwen, Regulatory Affairs Leader

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Wei Liwen Regulatory Affairs Leader

28 Feb. 2021