

EU DECLARATION OF CONFORMITY

Following the provisions of the medical devices regulation 2017/745.

We:

Manufacturer	Manufacturing Site
GE Vingmed Ultrasound AS Strandpromenaden 45 3191 Horten, Norway Single Registration Number (SRN): NO-MF-000000553	GE Healthcare Austria GmbH & Co OG Tiefenbach 15 A-4871 Zipf, Austria

Declare under our sole responsibility that the device:

Vscan Air SL

Basic UDI-DI: 8406821BUG00374HQ

Identification number (REF): Vscan Air SL

UDI-DI: 00195278660701

Intended Purpose: Vscan Air SL is a battery-operated general-purpose ultrasound probe intended for diagnostic ultrasound examinations and image guidance that is to be used with a host SW and display device.

GMDN Code: 40768--Extracorporeal ultrasound imaging system transducer, hand-held.

EMDN Code: Z11040201--TRANSCUTANEOUS ULTRASOUND PROBES

Class: IIa

Classification rule (Annex VIII): Rule 10 (Active MD for Diagnosis).

To which this declaration relates is in conformity with the requirements of the medical devices regulation 2017/745 that 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 (RoHS), and the directive 2014/53/EU on the radio equipment (RED).

- For the medical devices regulation 2017/745 (MDR)
 - Technical Documentation reference: **DOC2821804**, of the product to which this declaration relates.
 - EC certificate Number: **G10 023782 0130**
 - Conformity assessment procedure followed: Annex IX excluding Chapter II
 - Delivered by TÜV SÜD Product Service GmbH, identification number: **0123**
- For the directive 2011/65/EU (RoHS)
 - Technical Documentation reference: **DOC2821804**, of the product to which this declaration relates
- For the directive 2014/53/EU (Radio Equipment Directive)
 - Technical Documentation reference: **DOC2821804**, of the product to which this declaration relates
 - The conformity assessment procedure used for this declaration is Annex III of RED 2014/53/EU and the product will bear the CE-Marking accordingly.

Horten, Norway, 3-July-2023



Andrew Turner, Regulatory Affairs Leader

This EC declaration of conformity is the initial release for the Full Production of Vscan Air SL

ADDENDUM TO THE EC DECLARATION OF CONFORMITY dated 16 June 2023

PRODUCT Name	GEHC Cat # ^[1]	Part number ^[2]	REF ^[3]
Vscan Air SL	H45621BP	GP000180	Vscan Air SL
Compatible Medical Devices^[4]	GEHC Cat # ^[1]	Part number ^[2]/^[5]	REF ^[3]
Vscan Air	N/A	GP000251	Vscan Air R2 for iOS
	N/A	GP000241	Vscan Air R2 for Android
Non-MD OPTIONS AND ACCESSORIES ^[4]	GEHC Cat # ^[1]	Part number ^[2]	REF ^[3]
AC Adapters	H45621BT	GP200005	N/A
	H45621BV	GP200004	
	H45621CA	GP200007	
Vscan Air Charger	H45621BR	GP200304	N/A
	H45621CD	GP100309	

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. Compatible Devices, Options and Accessories are compatible with the Vscan Air SL, 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 SL 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 GP000251, GP000241 will not be seen on the device

Horten, Norway, 3-July-2023



Andrew Turner, Regulatory Affairs Leader

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