EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 720600 R000

Manufacturer: Philips Ultrasound LLC

Address:
22100 Bothell Everett Highway
Bothell
Washington
98021-8431
USA

Single Registration Number: US-MF-000002237

EU Authorised Representative: Philips Medical Systems Nederland B.V.

Address:
Veenpluis 6
5684 PC Best
The Netherlands

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2021-03-11**

Current Issue Date: **2023-01-05**

Starting Validity Date: **2023-01-05**

Expiry Date: **2026-03-10**

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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Diagnostic Ultrasound imaging systems including compatible non-sterile and end-user sterilizable transducers	Class IIa
Image guided intervention systems including compatible sterile coaxial needle trackers	Class IIa
Image review and quantification software	Class IIa

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference number	Action
2021-03-11	3099287	Issued
Current	3771001	Amended – Change of manufacturer name to Philips Ultrasound LLC. Addition of SRN of legal manufacturer. Approval of a critical sub-contractor and removal of list of critical subcontractors and crucial suppliers from certificate.

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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