By Royal Charter

EU Quality Management System Certificate

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

MDR 760300 R000

Manufacturer: Bioventus LLC

Address:
4721 Emperor Blvd.
Suite 100
Durham
North Carolina
27703
USA

Single Registration Number: US-MF-000008452

EU Authorised Representative: Emergo Europe B.V.

Address:
Westervoortsedijk 60
6827 AT Arnhem
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 devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional 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 Global Regulatory & Quality

First Issue Date: **2024-04-08**

Current Issue Date: **2025-02-18**

Starting Validity Date: **2025-02-18**

Expiry Date: **2029-04-07**

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Device Schedule: Class III and Class IIb devices

Class III, Implantable	Intended purpose
Durolane®	See MDR 776095

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

Device(s)	Risk Classification
Bone Growth Stimulation Instruments	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
2024-04-08	3562832	Issued
Current	30253841	Supplemented - Addition of Durolane® Device

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