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DECLARATION OF CONFORMITY

Manufacturer's Name	Bioventus LLC
Manufacturer's Address	4721 Emperor Boulevard, Suite 100 Durham, NC 27703 United States
Manufacturing Site(s) and Address	Q-Med AB Seminariegatan 21 Uppsala, 752 28 Sweden
Authorized Representative's Name and Address	Emergo Europe Westervoortsedijk 60 Arnhem 6827 AT Netherlands
Notified body's Name, address and Identification Number	BSI Group The Netherlands B.V. Notified Body Number 2797 Say Building, John M. Keynesplein 9 1066 EP Amsterdam Netherlands
Product Name	DUROLANE
Basic UDI-DI	B-00816986020181
Product Code(s)/Product Range and Description	See Table 1
Intended Purpose	<p>Intended Use: DUROLANE is intended to treat pain and improve function of synovial joints affected by osteoarthritis.</p> <p>Intended Patient Population: The product is intended to be used in an adult population with osteoarthritis. DUROLANE has not been tested in pregnant or lactating women or in children.</p> <p>Indications For Use: DUROLANE is indicated for the symptomatic treatment of mild to moderate knee or hip osteoarthritis. In addition, DUROLANE has been approved for the symptomatic treatment associated with mild to moderate osteoarthritis pain in the ankle, shoulder, elbow, wrist, fingers, and toes. DUROLANE is also indicated for pain following joint arthroscopy in the presence of osteoarthritis within three months of the procedure.</p>
Classification	Class III, per Rule 8 According to Annex VIII, Chapter III, of the Medical Device Regulations (EU 2017/745)
Single Registration Number (SRN)	US-MF-000008452
Common Specifications	Not Applicable

We hereby declare the listed medical device(s) complies with Medical Device Regulation (EU) 2017/745.

This declaration is made on the basis of:

Certificate Number MDR 760300 R000 and MDR 776095 R000 are issued by the Notified Body stated above, in accordance with conformity assessment requirement Annex IX of the Medical Device Regulation (EU) 2017/745.

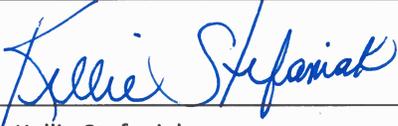
This EU Declaration of Conformity is issued under the sole responsibility of Bioventus, LLC.			
Signature		Date	09 OCT 2025
Name	Kellie Stefaniak		
Title / Function / Position	Global Vice President, Regulatory Affairs & Quality Bioventus LLC		

Table 1:

<u>Catalog number</u>	<u>Product Name</u>
1082010	DUROLANE®