



## DECLARATION OF CONFORMITY

We, Terumo Medical Corporation 265 Davidson Ave. Suite 320, Somerset, NJ 08873 USA  
being the manufacturer of:

Angio-Seal™ Vascular Closure Device

Hereby declares the following TMC facilities and products are in conformity with the provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017, concerning medical devices, and has been subject to the conformity assessment procedure laid down in Annex IX, based on a quality management system and on assessment of technical documentation, under the supervision of NSAI as Notified Body. All supporting documentation is retained under the premises of TMC. We declare no application has been lodged with any other notified body for the same products. This declaration is issued under the sole responsibility of the manufacturer.

<b>Product(s):</b>	6 Fr Angio-Seal VIP Vascular Closure Device (Model # 610132) 8 Fr Angio-Seal VIP Vascular Closure Device (Model # 610133)
<b>Basic UDI-DI:</b>	38970AS6S
<b>Classification:</b>	Class III, Rules 8 and 18 per Annex VIII MDR 2017/745
<b>GMDN Code(s):</b>	60710 - Femoral artery compression plug, collagen
<b>SRN No.:</b>	US-MF-000019594
<b>EC Certificate No.:</b>	745.019
<b>Applicable Quality System Standards:</b>	ISO 13485:2016 / EN ISO 13485:2016
<b>Notified Body:</b>	NSAI 1 Swift Square, Northwood, Santry, Dublin 9, Ireland D09A0E4
<b>Notified Body Number:</b>	0050
<b>EU Authorized Representative:</b>	Terumo Europe, N.V. Interleuvenlaan 40, 3001 Leuven, Belgium
<b>Place of Issue:</b>	United States of America

5/18/2023.  
Issue Date

  
John Boselli  
Sr. VP, Quality and Regulatory Affairs