TMC - Declaration of Conformity

Terumo Medical Corporation (TMC) hereby declares that the following TMC facilities and products are in conformity with the provisions of the EC Council Directive 93/42/EEC of 14 June 1993, as amended, concerning medical devices, and has been subject to the conformity assessment procedure laid down in Article 11.1 (a) of the Directive, relating to the "Full Quality Assurance System" set out in Annex II, and by certification of Annex II.3 and Annex II.4 under the supervision of BSI 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.

Legal Manufacturer Address:	Terumo Medical Corporation 265 Davidson Ave, Suite 320, Somerset, NJ 08873 USA
European Representative:	Terumo Europe, N.V. Interleuvenlaan 40, 3001 Leuven, Belgium
Product Type:	Vascular Closure Device
Product Name(s) and Model Number(s):	**FemoSeal Vascular Closure System** (C11202)
Classification:	Class III per Annex IX of the MDD 93/42/EEC, Rule 8
GMDN Code(s):	58871 - Femoral artery compression plug, synthetic polymer
EC Certificate No and Expiration Date:	Certificate Annex II No: CE 664635 (Expiration: 19 January 2022) Certificate Annex II.4 No: CE 664637 (Expiration: 19 January 2022)
Applicable Quality System Standards:	ISO 13485:2016 / EN ISO 13485:2016
Notified Body:	BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP Amsterdam The Netherlands P.O. Box 74103, 1070 BC Amsterdam, The Netherlands
Notified Body Number:	2797

Signature:

John Boselli
Sr. VP of Quality and Regulatory Affairs

Issue Date:

8/20/2019
Issue Date