EU MDR Declaration of Conformity (DoC)

Manufacturer:	Covidien llc 15 Hampshire St Mansfield, MA 02048 USA
Manufacturer SRN:	US-MF-000028763
Manufacturing Site:	Covidien 60 Middletown Avenue North Haven, CT 06473 USA Further processed in: Covidien (U.S.S.C Puerto Rico Inc.) Building 911-67, Sabanetas Industrial Park, 00731 Ponce, Puerto Rico USA
Authorized Representative:	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Authorized Representative SRN:	NL-AR-000006050
Notified Body:	TÜV SÜD Product Service GmbH 0123 Ridlerstraße 65 80339 München / Munich Germany
Conformity Assessment Certificate(s):	G10 077608 0096 EU Quality Management Certificate (MDR) expiring 2027-07-18
Conformity Assessment Procedure:	Annex IX, Chapter I and III in conjunction with Annex IX Chapter II
Risk Class:	Class IIb Implant
Classification Rule:	Rule 8
Intended Purpose:	The intended purpose of the device is fixation of prosthetic material or soft tissue approximation.

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Date: 2026.05.21 08:53:53 EEST
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Location: Moldova
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Statement:

We, Covidien llc, hereby declare under our sole responsibility that the product(s) specified herein conform to EU Medical Device Regulation 2017/745 and relevant Union Legislation that provides for the issuing of an EU Declaration of Conformity.

Union Legislation	Applicable Declaration of Conformity Document Number
Not applicable	Not applicable

Place: North Haven, CT, USA

Name: Lacee Levesque

Title: Regulatory Affairs Manager

Signature: 

Date: November 18, 2025

Products Covered

Product Description	Medtronic Product Identifier CFN	Basic UDI-DI
ProTack™ Auto Suture™ Fixation Device	174006	0763000B00005778A

Common Specification(s)

The following common specifications were used to demonstrate conformity: Not applicable

Number	Date of Issue	Title
Not applicable	Not applicable	Not applicable

Revision History

Revision	Date Effective	Description of Change
A	See CAP Agile	Initial release of document
B	See CAP Agile	Revise Product Brand Name
C	See CAP Agile	Added MDR G10 Approval Certificate information
D	See CAP Agile	DoC transferred to updated DoC template revision, D00009859 revision F. Added correct Manufacturing site
E	See CAP Agile	Updated the Quality Management cert

Digitally signed by Triboi Cătălina
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