

**Statement according to
Article 22, paragraph 2 of the EU MDR 2017/745**

We,

B. Braun Surgical S.A.
Ctra. de Terrassa, 121
08191 Rubí (Barcelona), Spain

hereby declare that the **Non Sterile** procedure pack

**SKIN SUTURE PACK DAFILON
Art. nº 75625**

See enclosed procedure pack content.

Consisting of a combination of devices bearing a CE marking with the following other devices or products as indicated below, in a manner that is compatible with the intended purpose of the device or other products and within the limits of use specified by their manufacturers, in order to place them on the market as procedure pack:

- other devices bearing the CE marking;
- in vitro* diagnostic medical devices bearing the CE marking in conformity with Regulation (EU) 2017/746;
- other products which are in conformity with legislation that applies to those products only where they are used within a medical procedure or their presence in the procedure pack is otherwise justified

whereby:

- a) The mutual compatibility of the devices and, if applicable other products, has been verified in accordance with the manufacturers' instructions and have carried out their activities in accordance with those instructions;
- b) The procedure pack has been packaged, and supplied relevant information to users incorporating the information to be supplied by the manufacturers of the devices or other products which have been put together
- c) The activity of combining devices and, if applicable, other products as procedure pack has been subject to appropriate methods of internal monitoring, verification, and validation.

Rubí, 04.05.2023

Sílvia Orús
Global Regulatory Affairs Manager
CoE, OR Supply
B. Braun Surgical, S.A.

Dr. Pau Turon, PhD (Chem), PhD (B.Adm.)
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B. Braun Group (Spain)

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Qty.	Model #	Product description				
6	0932132	SUT. DAFILON®	4/0	45cm	DS16	
6	0932205	SUT. DAFILON®	4/0	45cm	DS19	
6	0932353	SUT. DAFILON®	3/0	45cm	DS24	
6	0932477	SUT. DAFILON®	2/0	45cm	DS30	

Title: 75625 Statement of Art.22.2 for Procedure Packs_as non sterile MDR_20230504 Initiator: Maria del Carmen ? Gutierrez

This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

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