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

We,

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

hereby state that the Non Sterile procedure pack or System *(Indicate as applicable)*

HISTOACRYL FLEXIBLE PACK 5
Art. nº 1051250P

See enclosed procedure pack content.

Consisting of a combination of devices bearing a CE marking with the following other devices or products 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 a procedure pack or system (indicate as applicable):

☐ other devices bearing the CE marking;

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 or system 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 a procedure pack or system has been subject to appropriate methods of internal monitoring, verification, and validation.

Rubí, 25.03.2024

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

Dr. Pau Turon, PhD (Chem), PhD (B.Adm.)
VP Research and Development.
B. Braun Group (Spain)

Effective

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Qty.	Model #	Product description
5	1051250	**HISTOACRYL FLEX 0.5 ML**
5	1050079	**HISTOACRYL TIP**

Effective

Title: Statement Art.22.2 ppacks_non sterile MDR_Hist Flex Pack-1051250P.DOCX Initiator: Agusti ? Cot del Valle

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

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