

Declaration according to Article 12, paragraph 2 of the Directive 93/42/EEC

We,

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

hereby declare that the Non Sterile system

HISTOACRYL® LAPFIX X1 Art. nº 1052008

Consisting of a combination of sterile products listed below, has been:

- a) Combined verifying the mutual compatibility according to the instruction of the manufacturer
- b) The products have been packaged, where necessary, with relevant information for the user
- c) The whole activity is subject to our quality control and inspection procedures.

Model No.	Qty.	Product description
4606701V	1	JERINGA INJEKT 2 ML LUER-LOCK
1050044	2	HISTOACRYL BLUE 0,5ML
1052008C	1	HISTOACRYL CANNULA LAPFIX

Rubí, 4th of April of 2017

Silvia Orús

Global Regulatory Affairs Manager

CoE, Closure Technologies

B.Braun Surgical, S.A.

Dr. Pau Turón

R&D, Regulatory Affairs & Quality Director

CoE, Closure Technologies

B.Braun Surgical, S.A.

Art 12.2 Decl: Histoacryl Lapfix PACK 1052008 (1x) Date of approval: 4th April of April of 2017

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