

CE DECLARATION OF CONFORMITY

CEE MEDICAL DEVICES DIRECTIVE 93/42/EEC

PRODUCT MANUFACTURER: BRIX S. R. L.
ADDRESS: Parque Industrial Carcarañá
Ruta 9 km 348,5
(2138) Carcarañá – Provincia de Santa Fe - Argentina

EUROPEAN REPRESENTATIVE: CONCEPTOS FUNCIONES Y ESTETICA DENTAL IBERICA S.L.
ADDRESS: Gran Vía 8-10 1º 5b (08902) Hospitalet de Llobregat, Barcelona, España.

DECLARE UNDER THEIR RESPONSIBILITY THAT THE PRODUCT:

Name Brix 3000

ECRI-UMDNS Code: 15-584 GEL

Type: Gel for atraumatic removal in carious lesions. Syringes of 0.5, 1.0, 3.0 or 5.0 ml or tubes of 2, 3, 4, 5 or 6 ml multidose in individual boxes. Boxes containing 25, 50 or 100 units.

CONFORMS WITH THE REQUISITES OF THE DIRECTIVES

EC Directive 93/42/CEE Medical Devices Directive 93/42/CEE amended by Directive 2007/47/CE.
Transposition to Spanish Legislation in Real Decreto 1591/2009.

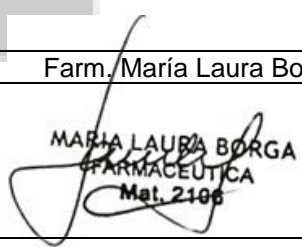
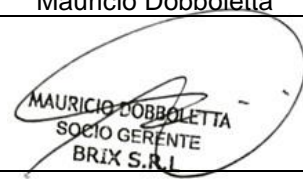
Classification (rule): Class I (rule 5)

Compliance with harmonized standards

ISO 13485:2013 / UNE-EN ISO 14971:2012 / UNE-EN ISO 10993
ANMAT Disp.Nº2318/02 T.O. 2004, ANMAT Disp.Nº 3266/13.

OTHER INFORMATION: A.F.E.Disp.6227/14 Legajo 2177 PM-2177-1
Design, Development, Manufacture and Sales of gel for a traumatic removal in carious lesions of dental use Certificate Nº216392-2017-AQ-ARG-NA printed and apostilled is being processed in Norway.

DATE: July 30th, 2017

	Farm. María Laura Borga	Mauricio Dobboletta
Signed	 MARIA LAURA BORGA FARMACEUTICA Mat. 2106	 MAURICIO DOBBOLETTA SOCIO GERENTE BRIX S.R.L.
Cargo / Function	Técnico Responsable Safety Officer	Gerente General General Manager