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.N°2318/02 T.O. 2004, ANMAT Disp.N° 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 N°216392-2017-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*