

CE DECLARATION OF CONFORMITY

DIRECTIVA PRODUCTOS SANITARIOS 93/42/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 LEGAL 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

Tipo / Type: Gel for atraumatic removal in carious lesions. Tubes of 2, 3, 4, 5 or 6ml multidose on individual boxes, or Syringes of 0.5, 1.0, 3.0 or 5.0 ml on individual boxes. Transport or export boxes contains 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)

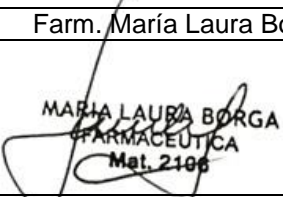

Compliance with harmonized standards

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 No.: 245221-2017-AQ-ARG-NA-PS Project No.: PRJC-551635-2016-MSC-ARG Initial certification date:
20 August 2017.
Certificacion valid until: April 1st, 2021

DATE: April 08th, 2019

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