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.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 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 Dobboletta
Signed	MARIA LAURA BORGA FARMACEUTICA Mat. 2106	MAURICIO DOBBOLETTA SOCIO GERENTE BRIX S.R.L.
Function	Técnico Responsable *Safety Officer*	Gerente General *General Manager*