Manufacturer's Declaration of Conformity

The devices listed in this declaration:

- comply with the applicable *Essential Principles for Safety and Performance* in Annex I of *Directive 93/42/EEC* amended by Directive 2007/47/EC regarding medical devices;
- have been classified according to the classification rules of Annex IX of the *Directive 93/42/EEC* amended by Directive 2007/47/EC regarding medical devices;
- have been subjected to the applicable conformity assessment in the procedure referred to in Annex II of *Directive 93/42/EEC* regarding medical devices.

The conformity of the devices listed is declared after drawing up the technical documentation.

Product Identification

Article Number	Product
	SMARTBRANE Resorbable Porcine Pericardium Collagen Membrane for Oral Tissue Regeneration Basic UDI: ++D740012
0121.200	10 mm x 10 mm
0121.201	15 mm x 20 mm
0121.202	20 mm x 30 mm
0121.203	30 mm x 40 mm
Intended Purpose	Indications for Use: SMARTBRANE is intended for use in intraoral/ maxillofacial surgery procedures as a material for placement in the area of periodontal defects, dental implants, bone defects or ridge reconstructions to aid in wound healing post-surgery. Intended Use: SMARTBRANE is intended to aid in the regeneration and integration of oral tissue components in guided bone regeneration (GBR) and guided tissue regeneration (GTR) procedures.
Harmonized Standards Applied	EN 556-1:2001/AC:2006, EN ISO 10993-1:2009/AC:2010, EN ISO 10993-5:2009, EN ISO 10993-12:2012, EN ISO 10993-17:2009, EN ISO 10993-18:2020, EN ISO 11137-1:2015/A2:2019, EN ISO 11137-2:2015, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-1:2006/AC:2009, EN ISO 11737-2:2020, EN ISO 13485:2016/AC:2016, EN ISO 14630:2009, EN ISO 14971:2012, EN ISO 15223-1:2016, EN ISO 22442-1:2020, EN ISO 22442-2:2020, EN ISO 22442-3:2007, EN 62366:2008

EMDN Code	Q010301
Term:	Periodontal Membranes
GMDN Code:	58709
Term:	Collagen dental regeneration membrane

Classification

After following the classification rules of Annex IX of the *Directive 93/42/EEC* amended by Directive 2007/47/EC regarding medical devices, the device listed in this declaration was classified as *Class III*; rule 17 applies to SMARTBRANE.

Conformity Assessment

According to the MDD Article 11, based on the classification of the product, the manufacturer, in order to affix the CE marking, followed the procedure relating to the EC declaration of conformity set out in *Annex II (full quality assurance)* of *Directive 93/42/EEC* amended by Directive 2007/47/EC regarding medical devices.

Manufacturer

Company name:	REGEDENT AG
Address:	Zollikerstrasse 144
Post code:	8008
City:	Zürich
Country:	Switzerland
Telephone:	+41 (0)44 700 37 77
Fax:	+41 (0)44 700 47 97
SRN:	CH-MF-000021048
CHRN:	CHRN-MF-20001790

Authorized Representative

Company name:	REGEDENT GmbH
Address:	Pfarrgasse 6
Post code:	97337
City:	Dettelbach
Country:	Germany
Telephone:	+49 (0)9324 604 99 27
Fax:	+49 (0)9324 604 99 26
SRN:	CH-AR-000009041

Certification

Certification:	EC Design - Examination Certificate
Standard:	Directive 93/42/EEC on Medical Devices, Annex II Section 4
Certificate valid from:	16/Sep/2020
Certificate is valid until:	26/May/2024
Certificate No.:	CE 615206

Certification:	EC Certificate – Full Quality Assurance System
Standard:	Directive 93/42/EEC on Medical Devices, Annex II excl. Section 4
Certificate valid from:	16/Sep/2020
Certificate is valid until:	26/May/2024
Certificate No.:	CE 614913

Notified Body:	BSI
Notified Body Number:	2797

This declaration of conformity is issued under the sole responsibility of the manufacturer indicated above and replaces the previous revision of the declaration of conformity issued for the products identified above.

If the device is modified in any way without the formal approval of the undersigned, this declaration of conformity becomes invalid.

This Declaration of Conformity is
issued on: May 26th, 2021
amended on: May 26th, 2023
valid until: May 26th, 2024

Approval

REGEDENT
REGEDENT AG
Zollikerstrasse 144
CH - 8008 Zürich
www.regedent.com

Lucia Calvi
CEO
REGEDENT AG

July 7th, 2023
Date