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.

Product Identification

Article Number	Product
	SMARTBRANE
0121.200	Resorbable Porcine Pericardium Collagen Membrane 10 mm x 10 mm
	SMARTBRANE
0121.201	Resorbable Porcine Pericardium Collagen Membrane 15 mm x 20 mm
	SMARTBRANE
0121.202	Resorbable Porcine Pericardium Collagen Membrane 20 mm x 30 mm
	SMARTBRANE
0121.203	Resorbable Porcine Pericardium Collagen Membrane 30 mm x 40 mm

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

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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

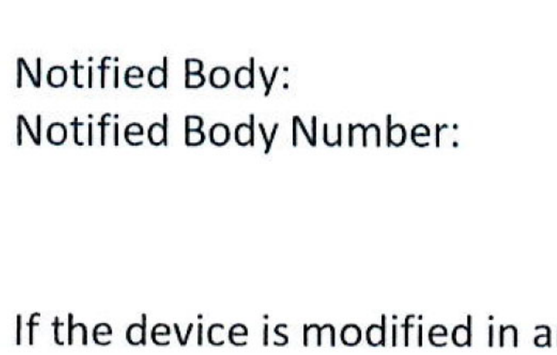
Certification:	EC Certificate – Full Quality Assurance System
Standard:	Directive 93/42/EEC on Medical Devices, Annex II excl. Section 4
Certificate valid from:	16/Sep/2020
Certificate is valid until:	26/May/2024
Certificate No.:	CE 614913

Notified Body:	BSI
Notified Body Number:	2797

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 valid as of September 16th, 2020.

Declaration Approval



September 16th, 2020

Date

Lucia Calvi
CEO
REGEDENT AG