

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. **CE 615206**
Issued To: **REGEDENT AG**
Zollikerstr. 144
8008 Zürich
Switzerland

In respect of:

SMARTBRANE - Resorbable Porcine Pericardium Collagen Membrane for Oral Tissue Regeneration

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2015-09-21**

Date: **2020-09-16**

Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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Supplementary Information to CE 615206

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
0121.200	SMARTBRANE Resorbable Porcine Pericardium Collagen Membrane	10mm x 10mm	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.	Class III
0121.201		15mm x 20mm		
0121.202		20mm x 30mm		
0121.203		30mm x 40mm		

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Certificate History

Date	Reference Number	Action
21 September 2015	10147004	First Issue.
19 April 2017	10168963	Change of animal tissue supplier.
18 February 2019	8690573	Approval of packaging change for Tyvek® 1073B packaging material affecting all products codes.
19 February 2019	8573307	Traceable to NB 0086.
02 June 2020	9772766	Approval of additional subcontractor for the manufacture of Smartbrane.
Current	3144114	Certificate Renewal. Change in storage temperature on label and in IFU. Change to scope from 'SMARTBRANE - Resorbable Pericardium Membrane' to 'SMARTBRANE - Resorbable Porcine Pericardium Collagen Membrane for oral tissue Regeneration' and device description from 'SMARTBRANE Resorbable Pericardium Membrane' to 'SMARTBRANE Resorbable Porcine Pericardium Collagen Membrane'. Change to device table format.

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