



Product Service

EC Certificate

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 17 07 32283 049

Manufacturer: **Biomatlante SA**
ZA les Quatre Nations

5, Rue Edouard Belin
44360 Vigneux de Bretagne
FRANCE



Product: **Collagen Implants**
Membranes

Model(s): **Resorbable Membranes based on Collagen**

Parameters: see Attachment

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. See also notes overleaf.

Report no.: 713111908_713076956

Valid from: 2018-01-12

Valid until: 2022-07-25

Date, 2018-01-12

Stefan Preiß



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Attachment for Certificate no G7 17 07 32283 049
valid from 2018-01-12

Supplement 001 dated 2018-01-12 (713111908_713076956)

Article no.	Model(s)	Type/Parameters	Material
BR-C1525	Membrane	15x25mm	Porcine collagen
BR-C2030	Membrane	20x30mm	Porcine collagen
BR-C3040	Membrane	30x40mm	Porcine collagen
05-9159252010	Membrane	15x25mm	Porcine collagen
05-9209302010	Membrane	20x30mm	Porcine collagen
05-9309402010	Membrane	30x40mm	Porcine collagen
BG1525	Membrane	15x25mm	Porcine collagen
BG1525x2	Membrane	15x25mm	Porcine collagen
BG2030	Membrane	20x30mm	Porcine collagen
BG3040	Membrane	30x40mm	Porcine collagen
0701EZC1525	Membrane	15x25mm	Porcine collagen
0901EZC1525	Membrane	15x25mm	Porcine collagen
0702EZC2030	Membrane	20x30mm	Porcine collagen
0703EZC3040	Membrane	30x40mm	Porcine collagen
8702453	Membrane	15x25mm	Porcine collagen
8702452	Membrane	20x30mm	Porcine collagen
8701470	Membrane	30x40mm	Porcine collagen
320-1525-00	Membrane	15x25mm	Porcine collagen
320-1525-01	Membrane	20x30mm	Porcine collagen
320-2030-00	Membrane	30x40mm	Porcine collagen
112.006	Membrane	15x25mm	Porcine collagen
112.007	Membrane	15x25mm	Porcine collagen
112.008	Membrane	20x30mm	Porcine collagen
112.009	Membrane	30x40mm	Porcine collagen

Munich, MHS-CRT, 2018-01-12

Stefan Preiß