Humeca
Skin Transplantation Technology

EU-Declaration of Conformity

Skin transplantation carriers
65263DOC-07/TK

We hereby declare that the distributed CE marked products, specified in the annexed products list, are covered by the "CE Marking of Conformity Certificate", reference number 65263CE01, issued on January 1, 1998 and delivered by DEKRA Certification B.V., Arnhem, The Netherlands, Notified Body with Identification Number 0344, and conform to the required technical documentation, in accordance with Annex VII of the "EC-Directive", the Council Directive 93/42/EEC of 14 June 1993, as amended by 2007/47/EC, concerning medical devices and fall under transitional provision 120(3).

In addition, we ensure and declare that the distributed CE marked products, as mentioned and falling within Class I sterile as per rule 1 for sterile non-invasive devices, meet the provisions of the EC-Directive which apply to them.

The products fall under the transitional provision article 120.

This declaration is supported by the Quality System certification based on the harmonized standard EN ISO 13485, Quality System Certificate with reference number: 2008072, issued on 1 August 2001 by DEKRA Certification B.V..

This Declaration of Conformity covers skin transplantation carriers and accessories as specified in the product list belonging to this declaration, and is valid for all products concerned bearing the CE marking and manufactured at the following site:

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On behalf of Humeca,

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Arnoud van Velzen
CEO

Annex: Products list 65263PL-07/TK
Date of issue: 25 Apr 2024
Valid until: 31 Dec 2028

Humeca
Skin Transplantation Technology

Products List

Skin transplantation carriers
65263PL-07/TK

This product list belongs to the Declaration of Conformity identified by 65263DOC-07/TK and specifies the CE marked products concerned that Humeca B.V. intends to distribute in conformity with the provisions of the Council Directive 93/42/EC of 14 June 1993, as amended by 2007/47/EC, concerning medical devices. The following list identifies the products by the product name and the article number.

Article Code	Item Description	Time related information
2.2/10	Micrografting gauze 1:2 with cork plate, box 10 pcs.	1998-01-01
2.3/10	Micrografting gauze 1:3 with cork plate, box 10 pcs.	1998-01-01
2.3/40	Micrografting gauze 1:3 with cork plate, box 40 pcs.	1998-01-01
2.4/10	Micrografting gauze 1:4 with cork plate, box 10 pcs.	1998-01-01
2.4/40	Micrografting gauze 1:4 with cork plate, box 40 pcs.	1998-01-01
2.6/10	Micrografting gauze 1:6 with cork plate, box 10 pcs.	1998-01-01
2.6/40	Micrografting gauze 1:6 with cork plate, box 40 pcs.	1998-01-01
2.9/10	Micrografting gauze 1:9 with cork plate, box 10 pcs.	1998-01-01
2.9/40	Micrografting gauze 1:9 with cork plate, box 40 pcs.	1998-01-01
6.V10-1.0	V-carrier for perforation 1:1; 1,0 mm	2007-10-18
6.V10-1.5	V-carrier for expansion 1:1,5; 1,0 mm	2007-10-18
6.V10-2.0	V-carrier for expansion 1:2; 1,0 mm	2010-05-19
6.V10-3.0	V-carrier for expansion 1:3; 1,0 mm	2007-10-18
6.V15-1.0	V-carrier for perforation 1:1, 1,5 mm	2007-10-18
6.V15-1.5	V-carrier for expansion 1:1,5; 1,5 mm	2007-10-18
6.V15-3.0	V-carrier for expansion 1:3; 1,5 mm	2007-10-18
6.V10-6.0	V-carrier for expansion 1:6; 1,0 mm	2014-07-07

KVK Netherlands Chamber of Commerce
Kamer van Koophandel
Legalized
14 NOV 2024
d9g31y348c
UTRECHT
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Electronic Certifying Stamp

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