

EU-Declaration of Conformity

Dermatomes and Dermatome Blades
65263DOC-2010TK

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 65263CE02, issued on 14 April 2004 and delivered by DEKRA Certification B.V., Arnhem, the Netherlands, Notified Body Identification Number 0344, and conform to the required technical documentation, in accordance with Annex V and VII of the "EC-Directive", the Council Directive 93/42/EEC of 14 June 1993, 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 IIA respectively Class IIA sterile 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 dermatomes and dermatome blades as specified in the products list belonging to this declaration, and is valid for all products concerned bearing the CE marking and manufactured at the following site:

Humeca B.V.
Oostermat 5
7623 CS Borne
The Netherlands

On behalf of Humeca,

 
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Ruud Nijlant
Chief operations officer

Annex: Products list 65263PL-2010/TK
Date of issue: 12 April 2021
Valid until: 12 April 2023

Products List

Dermatomes and Dermatome Blades
65263PL-2010/TK

This products list belongs to the Declaration of Conformity identified by 65263DOC-2010/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, amended by 2007/47/EC, concerning medical devices. The following list identifies the products by the product name and the article number.

Article number	Article description	Time-related information
Equipment		
4.D42STS	D42 dermatome, complete set, type 1200	25 April 2002
4.D80STS	D80 dermatome, complete set, type 2400	25 April 2002
Disposables		
5.D42BL10	Dermatome D42 blades, box 10 pcs.	25 April 2002
5.D80BL10	Dermatome D80 blades, box 10 pcs.	25 April 2002
5.BL4245	Dermatome blades, model 4245, for Aesculap/B. Braun dermatomes, box 10 pcs.	2 February 2005
5.BLPG10	Dermatome blades for Padgett dermatomes, box 10 pcs	6 November 2007
5.BLSB10	Blades for Sober dermatome, box 10 pcs.	6 November 2007
5.BLZM10	Blades for Zimmer dermatome 8801 and 8821, box 10 pcs	12 July 2016
5.BLSIL10	Humeca blade for Silver knife, box 10 pcs.	10 March 2021
5.BLHWC10	Humeca blade for Humby, Watson, Cobbett knives (16 cm, 6.3 in), box 10 pcs.	10 March 2021
5.BLHUL10	Humeca blade for Humby long knife (20 cm, 7.9 in), box 10 pcs.	10 March 2021

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