



Declaration of Conformity

PRODUCT IDENTIFICATION	
Product name	Model/number
Dermalux	Flex MD

MANUFACTURER		
Name of company	Address	Representative
Aesthetic Technology LTD.	Unit 211 Europa Boulevard, Warrington, Cheshire. WA5 7TN United Kingdom	Dale Needham

AUTHORIZED REPRESENTATIVE		
Name of company	Address	Telephone/email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	+31.70.345.8570 - phone EmergoEurope@ul.com

NOTIFIED BODY	
Notified Body and ID #	CE certificate number
BSi Netherlands Say Building, John M. Keynesplein 9, 1066EP Amsterdam	CE 660675

CONFORMITY ASSESSMENT		
Device classification	Route to compliance	Standards applied
Class IIa____ Rule 9____	Annex II of MDD 93/42/EEC Council Directive (excluding Section 4)	Optional

Aesthetic Technology declares that the above mentioned products meet the provision of the Council Directive 93/42/EEC for Medical Devices and Directive 93/42/EEC as transposed in the national laws of the Member States. This declaration is supported by the Quality System approval to ISO 9001 and ISO13485 issued by BSI.

COMPANY REPRESENTATIVE: Dale Needham

TITLE: Managing Director

DATE: 22/11/2021

SIGNATURE:



EC Declaration of Conformity

Manufacturer: Aesthetic Technology Ltd
Unit 211 Europa Boulevard
Warrington
Cheshire
WA5 7TN

Product Name: Dermalux Flex MD

Product Code: 1000004 Flex MD (UK)
1000006 Flex MD (CB UK)
1000053 Flex MD (US OTC)
1000059 Flex MD (US Rx)
1000014 Flex MD (EU)
1000007 Flex MD (CB EU)
1000023 Flex MD (International)
1000008 Flex MD (CB China)

Medical Device Assessment Route: Annex II (Excluding Section 4)

Notified Body: BSI Group
Say Building,
John M. Keynesplein 9,
1066EP Amsterdam
The Netherlands
Body No. 2797

We hereby declare that the medical devices(s) specified above meet the provisions of the Council Directive 93/42/EEC for Medical Devices. This declaration is supported by Quality Management System Approval to ISO 13485 and ISO 9001 issued by BSI.

All supporting documentation is retained at the premises of the manufacturer.

COMPANY REPRESENTATIVE: Dale Needham

TITLE: Managing Director

SIGNATURE:

Date: 22/11/2021