



## 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 support 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 device(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:**

A handwritten signature in blue ink, consisting of several loops and a long horizontal stroke at the end.

**Date:** 22/11/2021