CHEMENCE®
MEDICAL

Declaration of Conformity

Product Name:	derma+flex® Topical Skin Adhesive
Product Reference Numbers:	LB60406, LB60406- 01, LB60410, LB60410-01, LB60406V, LB60406V-01, LB60410V, LB60410V-01,
Legal Manufacturer:	Chemence Medical, Inc. 200 Technology Drive Alpharetta, GA 30005 USA
EC Representative:	Atlantico Systems, 34 Oldfield, Kingston, Galway, Republic of Ireland
Classification:	Class IIa per Annex IX of Council Directive 93/42/EEC
Classification Rule:	Four

We hereby declare that the above mentioned devices comply with the European Medical Devices Directive 93/42/EEC as amended by 2007/47/EEC and are in accordance with Annex V of the directive supported by the EC Certification 98334 issued by BSI Product Services (2797), BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Netherlands and adhering to the essential requirements in accordance with Annex I of the Directive 93/42/EEC.

This declaration is made on the basis of the Quality Assurance Certificate No. 97323 of BSI Group America, 12110 Sunset Hills Road, Suite 200 Reston, VA 20190, USA, and is also based on the existing Technical Documentation as per Annex VII, paragraph 3 of the directive 93/42/EEC.

All supporting documentation is retained at the premises of:

Chemence Medical, Inc.
200 Technology Dr.
Alpharetta, GA 30005
USA

This declaration is valid for the devices listed above in their original, unmodified packaging.

Dr. Kenneth N. Broadley
Chief Regulatory and Quality Officer

02 MAR 2020
Date