

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 755958 R0000

Manufacturer: Chemence Medical, Inc.

Address:

200 Technology Drive
Alpharetta
Georgia
30005
USA

Single Registration Number: US-MF-000000888

EU Authorised Representative: Atlantico Systems, Ltd.

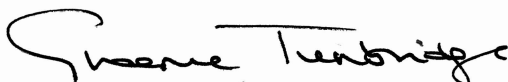
Address:

34 Oldfield
Kingston
Galway
H91 D8CX
Ireland

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-03-16**

Current Issue Date: **2023-03-16**

Starting Validity Date: **2023-03-16**

Expiry Date: **2028-03-15**

...making excellence a habit.™

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 755958 R0000

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Sterile Topical Skin Adhesives	Class IIa



First Issue Date: **2023-03-16**

Current Issue Date: **2023-03-16**

Starting Validity Date: **2023-03-16**

Expiry Date: **2028-03-15**

...making excellence a habit.™

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 755958 R0000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3506001	Issued



First Issue Date: **2023-03-16**

Current Issue Date: **2023-03-16**

Starting Validity Date: **2023-03-16**

Expiry Date: **2028-03-15**

...making excellence a habit.™