EU Quality Management System Certificate BE26/00000017

The management system of

Curan Medical BV

Barlhammerweg 26, Doetinchem, 7006 GE, Netherlands
SRN Number: NL-MF-000022827

has been assessed and certified as meeting the requirements of

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

For the following products
The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 16 January 2026 until 16 January 2031 and remains valid subject to satisfactory surveillance audits.
Recertification audit due before 16 July 2030

Issue 1. Certified since 16 January 2026

Authorised by
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Curan Medical BV

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

Class Is devices

MDN1202, MDS1005

Sterile PVC Nelaton Unisex Urinary Catheters with Leakage-Free Collection Bags
[Basic UDI-DI: 871865721PVC-CBQ6]

Sterile PVC Nelaton Urinary Catheters

Curan hydrophilic coated male and female catheters
[Basic UDI-DI: 871865721PVC-HCQP]

Curan hydrogel coated lady catheter
[Basic UDI-DI: 871865721PVC-CLQS]

Curan hydrogel coated man catheter
[Basic UDI-DI: 871865721PVC-CMQU]

Curan uncoated plain male and female catheters
[Basic UDI-DI: 871865721PVC-PLRZ]

Sterile PVC Free (TPU) Nelaton Urinary Catheters

Curan Hydrogel Coated Lady Catheter
[Basic UDI-DI: 871865721TPU-TCL8L]

Curan Hydrogel Coated Man Catheter
[Basic UDI-DI: 871865721TPU-TCM8N]

Curan Hydrophilic Coated Male and Female Catheters
[Basic UDI-DI: 871865721TPU-THC8H]

Sterile PVC Nelaton Urinary Catheters
[Basic UDI-DI: 871865721PVC-ADQ4]

Curan Advantage Catheter Hydrophilic Coated with Water Sachet Male, Female and Unisex
[Basic UDI-DI: 871865721TPU-TAD7W]

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Conditions for & limitation to the validity of the certificate:
For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available “on request" per email to NB1639@sgs.com.

Limitation: N/A

Certification is based on following reports: - BE/ANE/5/1063.QMD - S2A 4.1 + TFR 4.14
Authorized representative name and address (if relevant): N/A
Previous certificate number: N/A
Change in between this certificate and previous one: N/A