

EU Quality Management System Certificate BE26/00000017

The management system of

Curan Medical BV

The SGS logo is located in the top right corner. It consists of the letters 'SGS' in a bold, sans-serif font, with a vertical line to the right of the letters.

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

A handwritten signature in blue ink, appearing to be 'V. Siloret', is located below the validity text.

Authorised by

Virginie Siloret

Head of Certification and
Compliance

SGS Belgium NV NB1639

SGS House Noorderlaan 87 2030 Antwerp Belgium

t +32 (0)3 545-48-48 - www.sgs.com

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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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EU Quality Management System Certificate BE26/00000017,
continued

Curan Medical BV

SGS

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

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

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