EC Certificate Full Quality Assurance System: Certificate BE15/223575799

The management system of

Curan Medical BV

Barlhammerweg 26
7006 GE Doetinchem, The Netherlands

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 22 March 2021 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 9. Certified since 02 June 2015.

Certification is based on reports numbered BE/AMD 15/1063.QMD

Authorised by

Global Medical Devices Certification Manager

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Curan Medical BV

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 9

Detailed scope

Sterile PVC Nelaton urinary catheters including (ETO sterilised):
- Curan Hydrophilic Coated Male catheter
- Curan Hydrophilic Coated Female catheter
- Curan Hydrogel coated Lady catheter
- Curan Hydrogel coated Man catheter
- Curan uncoated Plain Male catheter
- Curan uncoated Plain Female catheter

Sterile PVC Nelaton Urinary Catheters (Irradiation sterilised):
- Curan Advantage Catheter Hydrophilic Coated - Male, Female and Unisex Catheters
- Sterile Nelaton Unisex Urinary Catheter with leakage-free collection bag (ETO sterilised):
Curan Closed System Hydrogel Coated Male and Female and Curan Complete Compact System Hydrogel Coated Male and Female

ETO Sterile TPU Nelaton urinary catheters:
- Curan Hydrophilic Coated Male
- Curan Hydrophilic Coated female
- Curan Man: compact male catheter in a sealed tube with hydrogel coating
- Curan Lady: compact catheter in sealed tube with hydrogel coating

Sterile TPU Nelaton urinary catheters (Gamma irradiation sterilised):
- Curan Advantage male catheter coated with hydrophilic coating and water sachet
- Curan Advantage female catheter coated with hydrophilic coating and water sachet
- Curan Advantage Unisex with hydrophilic coating and water sachet included male and female

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.