EU Quality Management System Certificate IN23/00001151

The management system of

Mediplus (India) Limited

1261-1262, M.I.E., Part-B, Bahadurgarh, Haryana-124507, India

SRN Number: IN-MF-000 007279

has been assessed and certified as meeting the requirements of

MDR EU Quality Management System certificate (Annex IX QMS)

For the following products

The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 10 November 2023 until 10 November 2028 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 10 May 2028

Issue 1. Certified since 10 November 2023

Certified activities performed by additional sites are listed on subsequent pages.

Authorised by
Virginie Siloret
Global Medical Device Certification Manager

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Mediplus (India) Limited

MDR EU Quality Management System certificate (Annex IX QMS)

Class IIa devices
MDN1202, MDS1005
Sterile I.V Cannula,
(Basic UDI-DI:890602530IVCANNULAK6)
Sterile I.V Cannula with safety features
(Basic UDI-DI:890602530SAFIVCANNULAXM)
Sterile 3-way stop cock
(Basic UDI-DI: 8906025303WSCD6)
Sterile 3-way stop cock with extension tubing
(Basic UDI-DI: 8906025303WSCWITHEXT4J)
Class I Sterile devices
MDN1202, MDS1005
Sterile Single-Use Injection Stopper, (Basic UDI-DI: 890602530INJSTOPT2)
Sterile Single-Use Male-Female Luer Lock, (Basic UDI -DI: 890602530MFLLFV)
Sterile Single-Use Luer Lock, (Basic UDI -DI: 890602530LCZR)
Sterile Single-Use Pressure Monitoring (Low or High Pressure) & Extension Tube,
(Basic UDI -DI: 890602530PMLMW)
Sterile Single-Use Needle Free Valve (Unidirectional Valve & Bidirectional Valve),
(Basic UDI -DI: 890602530NFVMK)

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: - IN/GUR/235607 - S2A 1.2
Authorized representative name and address (if relevant): Mdi Europa Gmbh, Langenhagener Stra 71, D 30855, Langenhagen, Germany

Previous certificate number: N/A
Change in between this certificate and previous one: N/A

Mediplus (India) Limited

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Issue 1
Sites
Mediplus (India) Limited 1261-1262, M.I.E., Part-B, Bahadurgarh, Haryana-124507, India
Mediplus (India) Limited Unit-2, Plot no 32, Sector 16, HSIDC, Bahadurgarh, Haryana-124507, India