



EU Quality Management Certificate



This is to certify that the company

SPM Medicare Pvt. Ltd.

B-40, Phase - II, Noida, Gautam Buddha Nagar
Uttar Pradesh, 201305
India

SRN: IN-MF-000011829

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745 **Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation**

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3.
Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	31619015 MDR2017Q
Certificate ID	1000323461
Effective date	2026-07-31
Expiry date	2029-08-08
Frankfurt am Main,	2026-07-30



DQS Medizinprodukte GmbH

Sven Hoffmann
Managing Director



Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main
DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.
The validity of the certification can only be verified by the QR-code.



Annex to EU Quality Management Certificate
SRN of Manufacturer: IN-MF-000011829
Certificate ID: 1000323461

Authorised Representative of the company:

CMC Medical Devices & Drugs SL

C/Horacio Lengo N18,
29006 Málaga,
Spain

SRN: ES-AR-000000293

Device categories and variants covered by this certificate according to Article 52:

Device category:	MDN 1211 - Non-active non-implantable devices for disinfecting, cleaning and rinsing
Product name:	Flush Syringe (Prefilled 0.9 % saline solution) With / Without Disinfectant Cap- Sterile / Sterile Fluid Path- 3ml, 5ml, 10ml, 20ml, 50ml Brand Name: EASY FLUSH
Risk classification:	IIB
Basic-UDI-DI:	89043798FSHEYE
Intended purpose:	Flush Syringe is intended for flushing compatible intravenous administration sets and indwelling intravenous access devices.
Device category:	MDN 1202 - Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis
Product name:	In-Line Arterial Blood Sampling Kit, Blister pack, with/without bubble remover 1ml/3 ml without needle Brand Name: a) EASY BLOOD COLLECT b) EASY BLOOD COLLECT AIR PRO
Risk classification:	Is
Basic-UDI-DI:	890437981BQ9BLP
Intended purpose:	In-line Arterial Blood Sampling Kit designed to obtain an in-line arterial blood specimen while maintaining a closed system.
Device category:	MDN 1202 - Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis
Product name:	Prefilled Syringe with 10% Glycerin Solution - 5ml, 10ml, 20ml, 30ml, 50ml Brand Name: EASY FILL GLYCASURE IIV
Risk classification:	Is
Basic-UDI-DI:	89043798ABS54QY
Intended purpose:	The Prefilled Syringe With 10% Glycerin Solution is intended for the safe and efficient inflation of indwelling urinary Foley catheter balloon.



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Device category: **MDN 1202 - Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis**

Product name: Prefilled syringe with sterile water - 5ml, 10 ml, 20ml, 30ml, 50ml
Brand Name:
EASY FILL AQUA

Risk classification: Is

Basic-UDI-DI: 89043798ABS54QY

Intended purpose: The Pre-filled Syringe with sterile water is intended for the safe and efficient inflation of indwelling urinary Foley catheter balloon, to retain the catheter in the bladder.

Examinations and tests performed:

ST_Assessment_Report_IRR_6-AW00_ST_Assessment_Report_IRR_ (1) (1)
5. MDR_Technical_Documentation_Assessment_Report_11192_MDR Technical Documentation(2)
(2)

Further conditions for or limitations to the validity of the certificate:

n/a

Reference to previous certificates:

Version	Date of Issue	Certificate-ID	Description of change
01	2026-07-30	1000323461	Transfer