EU Quality Management System Certificate

Certificate no.:	Initial certification date:	Valid Until:
C520058	09 November 2022	09 November 2027

This is to certify that the quality system of

MRK HEALTHCARE PRIVATE LIMITED

S. No. 153/P& 310, Panch Pippal,
Hansapur, Runi, Unjha-Patan Road,
Patan, Gujarat-384265, India

SRN: IN-MF-000019843

For design, production, and final product inspection/testing of:

Design, Production, and final inspection/testing of Disposable Medical Devices

Has been assessed and found to comply with respect to:

The conformity assessment procedure described in Annex IX, (Chapter I & III) of Regulation (EU) 2017/745 on Medical Devices

Place and date:
Høvik, 06 September 2023

For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

Digitally signed by Iarovoi Petru
Date: 2025.06.09 09:28:16 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Mariann Jeremiassen
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 1, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

MCR-CO-078-A V0.5

Certificate no.: C520058
Place and date: Høvik, 06 September 2023

Jurisdiction

Application of Regulation 2017/745 on medical devices, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Report No.	Issue Date
0.0	Original Certificate	2653253	09 November 2022
1.0	Correction	2653253	14 November 2022
2.0	Scope Extension	2653254	31 March 2023
3.0	Brand Addition	2895411	27 April 2023
4.0	Revision 2.0 Date Correction	NA	16 May 2023
5.0	Correction	NA	06 September 2023

Products covered by this Certificate:

Product Description	Product Name	Class
Sterile and Non Sterile Latex Surgical Gloves, Powdered and Powder free	Size: 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0 Brand: NULIFE, NUFIT, NUFLOW, MEDI-AID, NURAZ, PREMIERCARE, STARGLOVE, GSB, DV FRIENDS, SKRILL, NOVASOFT, FELMEDICA, BENESIT, PROTEX BY MILONAS, EASYFLOW, SANTE, GALENA, LDH, PARTNERS, SUPREME, SETINO, BRP, COMFORT, GLOMED PRO	IIa
Sterile and Non Sterile Latex Surgical Elbow length Gynaecology Gloves, Powdered and Powder free	Size: 6.5, 7.5, 8.5 Brand: NULIFE, NUFIT, NUFLOW, MEDI-AID, NURAZ, STARGLOVE, DV FRIENDS, NOVASOFT, BENESIT, PROTEX BY MILONAS, EASYFLOW, SANTE, GALENA, PARTNERS, SUPREME, SETINO, BRP, COMFORT, GLOMED PRO	IIa
Sterile and Non Sterile Latex Surgical Double pair Gloves, (High risk) Powder free	Size: Inner:6.0,6.5,7.0,7.5,8.0,8.5, 9.0 Outer: 5.5,6.0,6.5,7.0,7.5,8.0,8.5 Brand: NULIFE, NUFIT, NUFLOW, MEDI-AID, NURAZ, STARGLOVE, NOVASOFT, BENESIT, PROTEX BY MILONAS, EASYFLOW, SANTE, GALENA, PARTNERS, SUPREME, SETINO, BRP, COMFORT, GLOMED PRO	IIa
Sterile and Non Sterile Latex Surgical Double pair Gloves, (High risk) Powdered	Size: Inner:6.0,6.5,7.0,7.5,8.0,8.5, 9.0 Outer: 5.5,6.0,6.5,7.0,7.5,8.0,8.5	IIa

	Brand: NULIFE	
Sterile and Non Sterile Latex Surgical Under Gloves, Powder free	Size: 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0 Brand: NULIFE, NUFIT, NUFLOW, MEDI-AID, NURAZ, GLOMED PRO	IIa
Sterile and Non Sterile Latex Surgical Under Gloves, Powdered	Size: 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0 Brand: NULIFE	IIa
Sterile and Non Sterile Latex Surgical Microsurgery Gloves, Powder free	Size: 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0 Brand: NULIFE, NUFIT, NUFLOW, MEDI-AID, NURAZ, STARGLOVE, GSB, DV FRIENDS, NOVASOFT, BENESIT, PROTEX BY MILONAS, EASYFLOW, SANTE, GALENA, PARTNERS, SUPREME, SETINO, BRP, COMFORT, GLOMED PRO	IIa
Sterile and Non Sterile Latex Surgical Microsurgery Gloves, Powdered	Size: 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0 Brand: NULIFE	IIa
Sterile and Non Sterile Latex Surgical Orthopaedic Gloves, Powder free	Size: 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0 Brand: NULIFE, NUFIT, NUFLOW, MEDI-AID, NURAZ, STARGLOVE, NOVASOFT, BENESIT, PROTEX BY MILONAS, EASYFLOW, SANTE, GALENA, PARTNERS, SUPREME, SETINO, BRP, COMFORT, GLOMED PRO	IIa
Sterile and Non Sterile Latex Surgical Orthopaedic Goves, Powdered	Size: 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0 Brand: NULIFE	IIa
Sterile and Non Sterile Latex Surgical Ultra Gloves Beaded, Powdered and Powder free	Size: 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0 Brand: NULIFE, NUFIT, NUFLOW, MEDI-AID, NURAZ, GLOMED PRO	IIa
Sterile and Non Sterile Latex Surgical Ultra Gloves Beadless, Powdered and Powder free	Size: 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0 Brand: NULIFE, NUFIT, NUFLOW, MEDI-AID, NURAZ, STARGLOVE, GSB, DV FRIENDS, NOVASOFT, BENESIT, PROTEX BY MILONAS, EASYFLOW, SANTE, GALENA, PARTNERS, SUPREME, SETINO, BRP, COMFORT, GLOMED PRO	IIa
Sterile Male Incontinence Device (U-drain)	Size: Small / Ex-Small, Medium, Large / Ex-Large Brand: NULIFE, NUFIT, NUFLOW, MEDI-AID, NURAZ, AYSET, GALENA,	Is

	EASYFLOW, BRP	
Foley Balloon Catheter (FBC)	Two Way - 6Fr, 8Fr,10Fr,12Fr,14Fr,16Fr,18Fr, 20Fr, 22Fr, 24Fr, 26Fr, 28Fr, 30Fr Brand: NULIFE, NUFIT, NUFLOW, MEDI-AID, NURAZ, PARTNERS, GALENA, EASYFLOW, BRP, GLOMED PRO, GLOMED PRO SP	IIa
Foley Balloon Catheter (FBC)	Three Way- 16Fr,18Fr, 20Fr, 22Fr, 24Fr, 26Fr, 28Fr, 30Fr Brand: NULIFE, NUFIT, NUFLOW, MEDI-AID, NURAZ, PARTNERS, GALENA, EASYFLOW, BRP, GLOMED PRO, GLOMED PRO SP	IIa

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
MRK HEALTHCARE PRIVATE LIMITED Manufacturing Site	S. No. 153/P& 310, Panch Pippal, Hansapur, Runi, Unjha-Patan Road, Patan, Gujarat- 384265, India
MRK HEALTHCARE PRIVATE LIMITED Head Office	A-1201, Naman Midtown, Senapati Bapat Marg, Elphinstone Road, Mumbai-400013, India

EU Representative
OBELIS S.A, Bd. Général Wahis, 53 1030 Brussels, Belgium

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.
- For the class III devices covered this certificate is dependent on the continued validity of the EU Technical Documentation Assessment Certificate, covering the devices.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window

Specific conditions - Class I devices, Systems and Procedure Packs:

- For class I device being placed on the market in a sterile condition, Class I devices with a measurement function and class I devices being reusable surgical instruments covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 52(7) of the regulation.
- For system and procedure packs being placed on the market in a sterile condition, covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 22(3) of the regulation.
- For Custom Made Class III implantable device the certification only relates to the Quality management system. Technical documentation assessment and issuance of EU Technical Documentation Assessment Certificate does not apply.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EU declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
248929-2017-AQ-IND-NA-PS

Initial certification date:
16 January 2007

Valid:
23 October 2024 – 22 October 2027

This is to certify that the management system of

MRK HEALTHCARE PRIVATE LIMITED

Head Office :- A-1201, Naman Midtown, Senapati Bapat Marg, Elphinstone Road, Mumbai - 400013, Maharashtra, India

and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:

ISO 13485:2016 / EN ISO 13485:2016

This certificate is valid for the following scope:

Design & Manufacturing and Distribution and Sales of Sterile and Non-sterile Surgical Gloves, Examination Gloves, Male External Catheter, Foley Balloon Catheters;

Export and local trading of single use medical devices like IV set, BT set, Urine bags, Surgical/medical Devices made up of plastic or rubber products.

Place and date:
Høvik, 18 October 2024

NORWEGIAN ACCREDITATION
MSYS 018

For the issuing office:
DNV Product Assurance AS
Veritasveien 1, 1363 Høvik, Norway

Cecilie Gudesen Torp

Cecilie Gudesen Torp
Management Representative

Certificate no.: 248929-2017-AQ-IND-NA-PS
Place and date: Høvik, 18 October 2024

Appendix to Certificate

MRK HEALTHCARE PRIVATE LIMITED

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
MRK HEALTHCARE PRIVATE LIMITED	Manufacturing Site :- S. No. 153/P& 310, Panch Pippal, Hansapur, Runi, Unjha-Patan Road, Patan - 384265, Gujarat, India	Design & manufacturing and Distribution and Sales of Sterile and non-sterile Surgical Gloves, Examination Gloves, Male External Catheter, Foley Balloon Catheters.
MRK HEALTHCARE PRIVATE LIMITED	Head Office :- A-1201, Naman Midtown, Senapati Bapat Marg, Elphinstone Road, Mumbai - 400013, Maharashtra, India	Distribution and Sales of Sterile & Non – Sterile Surgical Gloves, Examination Gloves, Male External Catheters, Foley Balloon Catheters; Export and Local Trading of Single use medical devices like IV Sets, BT Sets, Urine Bags, Surgical/Medical Devices made up of Plastic or Rubber Products.

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
248929-2017-AQ-IND-NA-PS

Initial certification date:
16 January 2007

Valid:
23 October 2024 – 22 October 2027

This is to certify that the management system of

MRK HEALTHCARE PRIVATE LIMITED

Head Office :- A-1201, Naman Midtown, Senapati Bapat Marg, Elphinstone Road, Mumbai - 400013, Maharashtra, India

and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:

ISO 13485:2016 / EN ISO 13485:2016

This certificate is valid for the following scope:

Design & Manufacturing and Distribution and Sales of Sterile and Non-sterile Surgical Gloves, Examination Gloves, Male External Catheter, Foley Balloon Catheters;

Export and local trading of single use medical devices like IV set, BT set, Urine bags, Surgical/medical Devices made up of plastic or rubber products.

Place and date:
Høvik, 18 October 2024

NORWEGIAN ACCREDITATION
MSYS 018

For the issuing office:
DNV Product Assurance AS
Veritasveien 1, 1363 Høvik, Norway

Cecilie Gudesen Torp

Cecilie Gudesen Torp
Management Representative

Certificate no.: 248929-2017-AQ-IND-NA-PS
Place and date: Høvik, 18 October 2024

Appendix to Certificate

MRK HEALTHCARE PRIVATE LIMITED

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
MRK HEALTHCARE PRIVATE LIMITED	Manufacturing Site :- S. No. 153/P& 310, Panch Pippal, Hansapur, Runi, Unjha-Patan Road, Patan - 384265, Gujarat, India	Design & manufacturing and Distribution and Sales of Sterile and non-sterile Surgical Gloves, Examination Gloves, Male External Catheter, Foley Balloon Catheters.
MRK HEALTHCARE PRIVATE LIMITED	Head Office :- A-1201, Naman Midtown, Senapati Bapat Marg, Elphinstone Road, Mumbai - 400013, Maharashtra, India	Distribution and Sales of Sterile & Non – Sterile Surgical Gloves, Examination Gloves, Male External Catheters, Foley Balloon Catheters; Export and Local Trading of Single use medical devices like IV Sets, BT Sets, Urine Bags, Surgical/Medical Devices made up of Plastic or Rubber Products.