DNV BUSINESS ASSURANCE

MANAGEMENT SYSTEM CERTIFICATE

Certificate No. 2007-OSL-AQ-7902 / 2007-OSL-AQ-0696

This is to certify that the Management System of

MRK Healthcare Pvt Ltd.

at

Office: Byculla Service Industrial Premises, B4/B5, Basement, D. K. Marg, Sussex Road, Mumbai-400027, India
Works 1: S. No. 153/P& 310, Panch Pippal, Hansapur,Runi, Unjha-Patan Road, Patan-384265, Gujarat,India

has been found to conform to the Quality Management System Standard(s):

NS-EN ISO13485:2012/ISO13485:2003/ISO 9001:2008

This Certificate is valid for the following product or service ranges:

Manufacturing and Supply of Surgical, Examination Gloves, Male External Catheters, Penrose Tubings, I.V. Cannulaes with PTFE Catheters, Three-way Stopcocks, Single use medical devices like IV Sets, BT Sets, Catheters & Tubes, Foley Balloon Catheters, Urine Bags, Cord Clamps, Nebulizers, Electrical Needle Destroyers & Syringe Cutters. Export and Local Trading of Surgical/ Medical Devices made up of Plastic, Rubber, Non-Woven Fabrics and Allied Products.

Initial Certification date:
16 January 2007

Place and date:
Høvik, 22 December 2015

for the Accredited Unit:
DET NORSKE VERITAS
CERTIFICATION AS, NORWAY

Eugenie Winger Husebye

The audit has been performed under the supervision of

Atonu Dutta
Lead Auditor

NORWEGIAN ACCREDITATION
MSYS 002

Eugenie Winger Husebye
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.
This Certificate has been digitally signed. See www.dnv.com/digitalsignatures for more info
HEAD OFFICE. Det Norske Veritas AS, Veritasveien 1, 1322 Hovik, Norway. Tel: +47 67 57 99 00 Fax: +47 67 57 99 11 - www.dnv.com

Digitally signed by Iarovoi Petru
Date: 2019.03.20 16:14:15 EET
Reason: MoldSign Signature
Location: Moldova

EC Certificate
Full Quality Assurance System

A DNV GL & NEMKO COMPANY

Certificate No.:	Project No.:	Valid Until:
239534-2017-CE-IND-NA-PS	**PRJC-535567-2015-MSL-IND**	**06 September 2022**

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-384265, Gujarat, India

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

Disposable Medical Devices

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H2) of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

FIRMA DE PRODUCERE ȘI COMERȚ "SOGNO" S.R.L. REPUBLICA MOLDOVA, mun. CHIȘINĂU IDNO 1004600013854 Sogno S.R.L.

Place and Date:
Høvik, 09 September 2017

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL NEMKO PRESAFE AS

Tone Kolpus

Tone Kolpus

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

EC Certificate
Full Quality Assurance System

A DNV GL & NEMKO COMPANY

Certificate No.: **239534-2017-CE-IND-NA-PS**

Project No.: **PRJC-535567-2015-MSL-IND**

Valid Until: **06 September 2022**

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift for Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original certificate	2017-09-06

Products covered by this Certificate:

Product Description	Product Name	Class
Surgical Rubber Gloves and Speciality Gloves	Surgical latex gloves - sterile & non-sterile (Powdered Gloves, Powder Free Chlorinated Gloves, Powder Free Polymer Coating Gloves) Elbowlength gynaecology procedure latex gloves - sterile & non-sterile (Powdered Gloves, Powder Free Chlorinated Gloves, Powder Free Polymer Coating Gloves) Double pair speciality gloves (high risk gloves) - sterile (Powdered Gloves, Powder Free Chlorinated Gloves, Powder Free Polymer Coating Gloves) Orthopaedic speciality gloves - sterile (Powdered Gloves, Powder Free Chlorinated Gloves, Powder Free Polymer Coating Gloves) Micro surgery speciality gloves - sterile (Powdered Gloves, Powder Free Chlorinated Gloves, Powder Free Polymer Coating Gloves) Ultra Nulife sterile surgical gloves (beadless & beaded gloves) (Powdered Gloves, Powder Free Chlorinated Gloves, Powder Free Polymer Coating Gloves)	IIa
Examination Latex Gloves	Sterile & non-sterile (Powdered Gloves, Powder Free Chlorinated Gloves, Powder Free Polymer Coating Gloves)	Is
Examination Latex-free Gloves	Sterile & non-sterile (Powdered Gloves, Powder Free Chlorinated Gloves, Powder Free Polymer Coating Gloves)	Is

EC Certificate
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Certificate No.: **239534-2017-CE-IND-NA-PS**

Project No.: **PRJC-535567-2015-MSL-IND**

Valid Until: **06 September 2022**

Non-active devices for emergency & intensive care	Penrose Drainage Tubing	IIa
Non-active devices for emergency & intensive care	Male Incontinence device (U-Drain)	Is

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

MRK HEALTHCARE PRIVATE LIMITED, . No. 153/P& 310, Panch Pippal, Hansapur, Runi, Unjha-Patan Road, Patan-384265, Gujarat, India

EU Representative

Obelis s.a, 34, Av de Tervuren, Bte 44, B-1040 Brussels, BELGIUM

EC Certificate
Full Quality Assurance System

A DNV GL & NEMKO COMPANY

Certificate No.:	Project No.:	Valid Until:
239534-2017-CE-IND-NA-PS	PRJC-535567-2015-MSL-IND	06 September 2022

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 Presafe of any intended updating of the quality system and Presafe 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. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

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

Conformity declaration and marking of product

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

End of Certificate