DNV BUSINESS ASSURANCE

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

Certificate No. 109802-2012-CE-IND-NA Rev. 2.0
This Certificate consists of 4 pages

This is to certify that the Quality Management System of

MRK HEALTHCARE PVT LTD

B4/B5, Byculla Service Industries, D. K. Marg, Sussex Road, Byculla, Mumbai-400027, 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 H) of Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply

Further details are given overleaf

Place and date:
Høvik, 02 May 2014

For DET NORSKE VERITAS CERTIFICATION AS
NORWAY

Aud Løken Eiklid
Certification Manager

NORWEGIAN ACCREDITATION
PROD 002

Notified Body No.:
0434

This Certificate is valid until:
19 January 2017

Mariann Jeremiassen
Technical Reviewer

This Certificate has been digitally signed. See www.dnv.com/digitalsignatures for more info

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
	Original certificates no.: 2007-OSL-MDD-0026 and 2007-OSL-MDD-0027	2007-01-19
	Recertification	2012-01-19
1.0	Manufacturer's name change	2012-09-19
2.0	**Cancellation of the non-active medical device for disinfecting, cleaning, rinsing - NuFloor**	**2014-05-02**

Products covered by this Certificate

Product	Product Types/Models/Variants	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
Non-active devices for emergency & intensive care	Foley Balloon Catheter (three way and two way), Penrose Drainage Tubing, IV Cannula with PTFE Catheter, Three-way Stop Cock, Infusion Set, Blood Administration Set, Blood Donor Set, Parental Dialysis Set, Measured Volume Set, Scalp Vein Set, Urethral Catheter, Chest Drainage Catheter, Abdominal Drainage Kit, PVC Corrugated Drainage Sheet, Ryle's Tube, Infant Feeding Tube,	IIa

	Rectal Tube, Lavins Tube, Karman Cannula, Nasal Oxygen Catheters, Suction Catheters, Guedel Airway, A.V. Fistula, Combiluer Lock, Flow Regulator, T.U.R. Set, Extension Tube, Extension Tube with 3 way stop cock, Pressure Monitoring Extension Tube, Injection stopper, Luer lock, Luer cap, Blood Lancet, Nelaton Catheter , Thoracic Drainage Catheter, Microdrip Set, Obdurator	
Non-active devices for emergency & intensive care	Male Incontinence device (U-Drain), Stomach Tube, Nasal Gastric Tube, Infant Mucus Extractor, Urine Bag, Umbilical Cord clamp	Is

The complete list of devices is filed with the Notified Body.

Sites covered by this certificate: S. No. 153/P, Panchpippal, Hansapur, Unjha-Patan Road, Patan, India

EU Representative:
Obelis s.a, 34, Av de Tervuren, Bte 44, B-1040 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 local DNV Office of any intended updating of the quality system and DNV 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 DNV 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 DNV.

END OF CERTIFICATE