NOTIFIED BODY CONFIRMATION LETTER

Certificate Number

C676133

Status

Issued/Current

Scheme

Medical Device Regulation (EU) 2017/745 (NoBo# : 2460)

Accreditation Body

NoMA

Company Name

KANAM LATEX INDUSTRIES PRIVATE LIMITED

Initial Issued Date

March 13, 2024

Current Issued Date

March 13, 2024

Valid Until

December 31, 2028

Scope

Design, Production and final inspection/testing of Sterile and Non-Sterile Surgical Latex Gloves & Sterile Surgical Synthetic Gloves. Design, Production, and final inspection/testing Sterile Examination Latex Gloves & Sterile Examination Synthetic Gloves.

SITES: (1)

No.	1
Name	KANAM LATEX INDUSTRIES PRIVATE LIMITED

Scope	Design, Manufacture, Marketing of Sterile and Non -- Sterile Surgical Latex Gloves, Sterile Surgical Synthetic Gloves, Sterile Examination Latex Gloves and Sterile Examination Synthetic Gloves.
Address	12/67C, Ananthanadarkudy, Asaripallam P.O, Nagercoil, Kanyakumari - 629201, Tamil Nadu, India

Notified Body Confirmation Letter Reference: C676133

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, DNV Product Assurance AS, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number NB 2460 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Kanam Latex Industries Private Limited

12/67 C, Ananthanadarkudy, Asaripallam P.O., Nagercoil – 629 201,
Kanyakumari District,
Tamil Nadu, India

SRN Number: IN-MF-000022741

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

Place and date:
Høvik,13.03.2024

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

Menaka Singh
Management Representative

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function.
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
1.Device name : Sterile Latex Surgical Gloves Powdered **Brand Name:** **Regular Cuff** Comfort, Danglove, DOC, IDA, Kaltex, Kings, Master, Naturflex, Parasel, Surgicare DH, Serjun, Sterigant+, Surgicare B&G, Surgicare Lowpro, Surgicare E, Kaltex EC,Comfort Powdered, Santex Powdered, Medimax, Surgicare, Handsafe, Med - Comfort, Medix Lowpro, Pharco Lowpro, Solidor, Maboko, Bromed, Unicut, IMS, Juski, Surgicare Style 41, Dona Sensitive, Mumu, No.1 Glove. **Long Cuff – Gynaecological Gloves** Dona Sensitive 410, Gynamed, Sterigant+, Surgicare, Medix Gyna 480, Kings, Juski. **Basic UDI DI : 806363LSGPMQ**	**IIa**	**Product Description : Latex Gloves (Regular & Long Cuff)** **Product Name :** Surgical Gloves Powdered Gynaecological Gloves (Powdered) **(Name Change Only)**	10723-2017-CE-IND-NA-PS Rev.3.0 DNV Product Assurance AS 2460 Appendix to EC Certificate (Rev.00 to Rev.05)
2. Device name : Sterile Latex	**IIa**	**Product Description :** Latex	10723-2017-CE-IND-

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Surgical Gloves Powder Free **Brand Name :** **Regular Cuff** Comfort PF, Kaltex Plus, Surgicare Plus, Surgicare Plus DH, Surgicare Supreme, Comfort Powder-Free, Medibase, Bromed, IDA. **Long Cuff – Gynaecological Gloves** Dermagel Gyno, DOC, Gynoglove, Naturflex Gine, Surgicare Plus, Bromed, Surgicare **Basic UDI DI :** 806363LSGFM4		Gloves (Regular & Long Cuff) **Product Name :** Surgical Gloves (Powder Free) Gynaecological Gloves (Powder Free) **(Name Change Only)**	NA-PS Rev.3.0 DNV Product Assurance AS 2460 Appendix to EC Certificate (Rev.00 to Rev.05)
Device name : Sterile Latex Surgical Gloves Powder Free Polymer Coated **Brand Name :** **Regular Cuff** Surgicare Sensitive, Dermagel, Dermagel Dual, DOC, Surgicare Dual, Surgicare Premier, Surgicare Premier G,Handsafe PF, HSO Crystal, Med-Comfort, Pharco Premier, Dermagel Coated, Medix Premier, Bromed Plus, Santex Powder free, Marque Conseil, Kaltex EC, Naturflex, Santex PF, Nobafeel, IDA, IMS, Juski, Surgicare Style 41 PF, Dona Sensi plus, Mumu, Surgicare Underglove. **Long Cuff – Gynaecological Gloves** Medix Premier, Surgicare Premier, Gleco glove, Naturflex Gine, Bromed, Dermagel Gyno, GynoGlove, Nobafeel Gyn, Juski. **Basic UDI DI :** 806363LSGFM4	**IIa**	**Product Description :** Latex Gloves (Regular & Long Cuff) **Product Name :** Surgical Gloves (Powder Free Polymer Coated) Gynaecological Gloves (Powder Free Polymer Coated) **(Name Change Only)**	10723-2017-CE-IND-NA-PS Rev.3.0 DNV Product Assurance AS 2460 Appendix to EC Certificate (Rev.00 to Rev.05)

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device name : Sterile Latex Surgical Gloves Powder Free Polymer Coated (Micro/Neuro) **Brand Name :** **Regular Cuff** Biosafe Micro, Danglove Micro, Micro, Dermagel Micro, DOC Micro, Microtex, Surgicare Micro, Surgicare Neuro, Nobafeel sensitive. **Basic UDI DI :** 806363LSGFM4	**IIa**	**Product Description :** Latex Gloves (Regular & Long Cuff) **Product Name :** Micro Surgery Gloves (Powdered & Powder Free) **(Name Change Only)**	10723-2017-CE-IND-NA-PS Rev.3.0 DNV Product Assurance AS 2460 Appendix to EC Certificate (Rev.00 to Rev.05)
Device name : Sterile Latex Surgical Gloves Powder Free Polymer Coated (Orthopaedic) **Brand Name :** **Regular Cuff** Biosafe Ortho, Danglove Ortho, Dermagel Orthopedic, DOC Ortho, Naturflex Orto, Orthopeg, Surgicare Ortho, Med-Comfort Ortho, Surgicare Ortho Style 41 PF **Basic UDI DI :** 806363LSGFM4	**IIa**	**Product Description :** Latex Gloves (Regular & Long Cuff) **Product Name :** Surgical Orthopaedic Gloves (Powdered & Powder Free) **(Name Change Only)**	10723-2017-CE-IND-NA-PS Rev.3.0 DNV Product Assurance AS 2460 Appendix to EC Certificate (Rev.00 to Rev.05)
3. Device name :Sterile Synthetic PolyChloroprene Surgical Gloves Powder Free **Brand Name :** **Regular Cuff** Dermagel Neopren, Naturflex Neo,Naturflex Neo 2.0, Surgicare Neoprene, Surgicare Neoprene Soft, Syntec Neoprene, Hosp Neoprene Soft, Bromed Neoprene Soft, Sterisense green, Syntec, Nobafeel Syntex. **Basic UDI DI :** 806363SPGFN6	**IIa**	**Product Description :** Synthetic Surgical Gloves (Regular and Long cuff) **Product Name :**Non-Latex synthetic Surgical Gloves (Powder Free)- Poly chloroprene **(Name Change Only)**	10723-2017-CE-IND-NA-PS Rev.3.0 DNV Product Assurance AS 2460 Appendix to EC Certificate (Rev.00 to Rev.05)

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
4. Device name : Sterile Synthetic Poly Isoprene Surgical Gloves Powder Free **Brand Name :** **Regular Cuff** Surgicare Isoprene, Superflex Poly Isoprene **Basic UDI DI :** 806363SIGFM3	**IIa**	**Product Description :** Synthetic Surgical Gloves (Regular and Long cuff) **Product Name :** Non-Latex synthetic Surgical Gloves (Powder Free)- Poly Isoprene **(Name Change Only)**	10723-2017-CE-IND-NA-PS Rev.3.0 DNV Product Assurance AS 2460 Appendix to EC Certificate (Rev.00 to Rev.05)
5. Device name :Sterile Latex Examination Gloves Powdered **Brand Name :** **Regular Cuff** DOC, Santex Sterile, Prohand, Naturflex, Kaltex, Team Power, Surgicare, Juski. **Long Cuff** Kaltex **Basic UDI DI :** 806363LEGPKJ	**Is**	**Product Description :** Latex Examination Gloves (Regular and Long cuff) **Product Name :**Sterile Examination Gloves (Powdered) **(Name Change Only)**	10723-2017-CE-IND-NA-PS Rev.3.0 DNV Product Assurance AS 2460 Appendix to EC Certificate (Rev.00 to Rev.05)
6. Device name :Sterile Latex Examination Gloves Powder Free **Brand Name :** **Regular Cuff** Danglove, High Protection, Kaltex, Naturflex, HSO Polytex, Surgicare, Nobaglove, Juski. **Long Cuff** Kaltex **Basic UDI DI :** 806363LEGFJW	**Is**	**Product Description :** Latex Examination Gloves (Regular and Long cuff) **Product Name :**Sterile Examination Gloves (Powder Free) **(Name Change Only)**	10723-2017-CE-IND-NA-PS Rev.3.0 DNV Product Assurance AS 2460 Appendix to EC Certificate (Rev.00 to Rev.05)
7. Device name :Sterile Synthetic Nitrile Examination Gloves Powder Free **Brand Name :** **Regular Cuff** Kaltex, Naturflex Nitrilo, Nitrylex Sterile, Prohand PF Nitrile, Hosp Nitrile **Long Cuff** Kaltex, Kaltex Nitrile	**Is**	**Product Description :** Synthetic Examination Gloves (Regular and Long cuff) **Product Name :** Sterile Nitrile Examination Gloves (Powder Free) **(Name Change Only)**	10723-2017-CE-IND-NA-PS Rev.3.0 DNV Product Assurance AS 2460 Appendix to EC Certificate (Rev.00 to Rev.05)

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Basic UDI DI : 806363SNGFMU			

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
NA	**NA**	**NA**	**NA**

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024.03.13	C676133	Initial issue

Lack of fulfilment of conditions

The following may render this letter of confirmation invalid:

- Lack of compliance to the requirements of Regulation (EU) 2023/607.
- Significant changes to design or intended purpose of the devices.
- Changes in the quality system affecting production.
- Periodical audits not held within the timeframe.

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
10723-2017-CE-IND-NA-PS Rev. 3.0	PRJC-188486-2009-PRC-IND	26 May 2024

This is to certify that the quality system of:

KANAM LATEX INDUSTRIES PRIVATE LIMITED

12/67C, Ananthanadarkudy, Asaripallam (PO), Nagercoil -629 201, Kanyakumari District, Tamil Nadu, India

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

Sterile and Non-Sterile Surgical Latex Gloves, Sterile Surgical Synthetic Gloves, Sterile Examination Latex Gloves and Sterile Examination Synthetic Gloves

Has been assessed with respect to:

THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX II EXCLUDING SECTION 4 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.

Place and date:
Høvik, 02 June 2020

NORWEGIAN ACCREDITATION

PROD 021

For:
DNV GL PRESAFE AS

Notified Body No.: 2460

Eugenie Winger Husebye

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html

Jurisdiction

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

Certificate history:

Revision	Description	Issue Date
0.0	Supersedes DNV GL (NB 0434) certificate No. 68085-2009-CE-IND-NA Rev. 4.0 following the transfer of Notified Body functions to DNV GL NEMKO Presafe AS (NB 2460).	08 August 2017
1.0	Extension in scope - new products (in bold) added	27 April 2018
2.0	Recertification Audit	18 May 2020
3.0	**New Brand addition in bold**	**02 June 2020**

Products covered by this Certificate:

Product Description	Product Name	Class
Latex Gloves (Regular & Long Cuff)	1.Surgical Gloves Powdered Size:5.5 to 9.0 Brand: Comfort, Danglove, DOC, IDA, Kaltex, Kings, Master, Naturflex, Parasel, Surgicare DH, Serjun, Sterigant+, Surgicare B& G, Surgicare Lowpro, Surgicare E, Kaltex EC, Comfort Powdered, Santex Powdered, Medimax, Surgicare, Handsafe, Med - Comfort, Medix Lowpro, Pharco Lowpro, Solidor, Maboko, Bromed**,** Unicut	IIa
	2. Gynaecological Gloves (Powdered) Size: 6.0,6.5 (S),7.0,7.5 (M),8.0,8.5 (L) Brand: Dona Sensitive 410, Gynamed, Sterigant+, Surgicare,Medix Gyna 480, **Kings**	IIa
	3. Surgical Gloves (Powder Free) Size:5.5 to 9.0 Brand: Comfort PF, Kaltex Plus,Surgicare Plus, Surgicare Plus	IIa

	DH, Surgicare Supreme, Comfort Powder-Free, Medibase, Bromed,**IDA**	
	4. Gynaecological Gloves (Powder Free) Size: 6.0,6.5 (S),7.0,7.5 (M),8.0,8.5 (L) Brand: Dermagel Gyno, DOC, Gynoglove, Naturflex Gine, Surgicare Plus, Bromed, **Surgicare**	IIa
	5. Surgical Gloves (Powder Free Polymer Coated) Size:5.5 to 9.0 Brand: Surgicare Sensitive, Dermagel, Dermagel Dual, DOC, Surgicare Dual, Surgicare Premier, Surgicare Premier G, Handsafe PF, HSO Crystal, Med-Comfort, Pharco Premier, Dermagel Coated, Medix Premier, Bromed Plus, Santex Powder free, Marque Conseil, Kaltex EC, **Naturflex,Santex PF**	IIa
	6. Gynaecological Gloves (Powder Free Polymer Coated) Size: 6.0,6.5 (S),7.0,7.5 (M),8.0,8.5 (L) Brand: Medix Premier, Surgicare Premier, Gleco glove, **Naturflex Gine , Bromed, Dermagel Gyno, GynoGlove**	IIa
	7. Micro Surgery Gloves (Powdered & Powder Free) Size:5.5 to 9.0 Brand: Biosafe Micro, Danglove Micro, Micro, Dermagel Micro, DOC Micro, Microtex, Surgicare Micro, Surgicare Neuro	IIa
	8. Surgical Orthopaedic Gloves (Powdered & Powder Free) Size:5.5 to 9.0 Brand: Biosafe Ortho, Danglove Ortho, Dermagel Orthopedic, DOC Ortho, Naturflex Orto, Orthopeg, Surgicare Ortho, Med-Comfort Ortho	IIa
2. Synthetic Surgical	1.Non-Latex synthetic Surgical Gloves	IIa

Gloves (Regular and Long cuff)	(Powder Free)- Poly chloroprene Size:5.5 to 9.0 Brand: Dermagel Neopren, Naturflex Neo,Naturflex Neo 2.0, Surgicare Neoprene, Surgicare Neoprene Soft, Syntec Neoprene, Hosp Neoprene Soft, Bromed Neoprene Soft, Sterisense green,**Syntec**	
	2. Non-Latex synthetic Surgical Gloves (Powder Free)- Poly Isoprene Size:5.5 to 9.0 Brand: Surgicare Isoprene, Superflex Poly Isoprene	IIa
3. Latex Examination Gloves (Regular and Long cuff)	1. Sterile Examination Gloves (Powdered) Size: XS, S, M, L & XL Brand: DOC, Santex Sterile, Prohand, Naturflex,Kaltex, Team Power, Surgicare	Is
	2. Sterile Examination Gloves (Powder Free) Size: XS, S, M, L & XL Brand: Danglove, High Protection, Kaltex, Naturflex, HSO Polytex, Surgicare	Is
4.Synthetic Examination Gloves (Regular and Long cuff)	1. Sterile Nitrile Examination Gloves (Powder Free) Size: XS, S, M, L & XL Brand: Kaltex, Naturflex Nitrilo, Nitrylex Sterile, Prohand PF Nitrile, Hosp Nitrile	Is

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
KANAM LATEX INDUSTRIES PRIVATE LIMITED	**12/67C, Ananthanadarkudy , Asaripallam (PO), Nagercoil -629 201, Kanyakumari District, Tamil Nadu, India.**

EU Representative
EMERGO EUROPE, Prinsessegracht 20,2514 AP, The Hague, The Netherlands Tel: (+31) 70 345 8570; Fax: (+31) 70 346 7299 mail: europe@emergogroup.com

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