EU TYPE-EXAMINATION CERTIFICATE MODULE B N° G-124-03429-20-Ed.1

FABBRICANTE *MANUFACTURER*

Azienda *Company*	KANAM LATEX INDUSTRIES PVT. LTD.
P. Iva *VAT no*	
Via *Street name*	12/67C, ANANTHANADARKUDY, ASARIPALLAM P.O., NAGERCOIL - 629 201
CAP *Postcode*	
Città (Prov.) *City*	TAMIL NADU KANYAKUMARI DISTRICT
Paese *Country*	INDIA

MANDATARIO *AUTHORISED REPRESENTATIVE*

Azienda *Company*	GARDENING - SRL
P. Iva *VAT no*	02625810995
Via *Street name*	VIA B. BOSCO 15/10
CAP *Postcode*	16121
Città (Prov.) *City*	GENOVA
Paese *Country*	ITALIA

Articolo *Item*	CHR
Marchio *Brand*	GARDENING
Descrizione *Description*	Guanto monouso di protezione contro rischi chimici e microorganismi *Protective disposable gloves against dangerous chemicals and micro-organisms*
Taglie *Size*	6-9
Categoria *Category*	III
Norme armonizzate applicate (in tutto o in parte) *Harmonised standards applied (or parts thereof)*	EN 420:2003+A1:2009, EN ISO 374-1:2016, EN ISO 374-5:2016
Livelli di prestazione e/o classe di protezione *Protection class and/or performance levels*	Fare riferimento alla/e pagina/e seguente/i. *Please refer to the following page(s).*
Tipo *Type*	C
Altre specifiche tecniche applicate *Technical specifications applied*	

CIMAC CERTIFICATIONS
A.N.C.I. Servizi s.r.l. a socio unico
CF e PIVA 07199040150
REG. Imprese n° 229059
Trib. Di Milano - REA n° 1147818
Sede legale:
Via Alberto Riva Villasanta, 3 - 20145 Milano
Sede Operativa:
Organismo notificato n. 0465
Via Aguzzafame 60/b
27029 Vigevano (PV) - Italy
+39 0381 84722
info@cimac.it - www.cimac.it

Norma *Standard*	**Livello di prestazione** *Level of performance*	**Livello** *Level*
EN 420:2003+A1:2009	Destrezza *Dexterity*	5

Norma *Standard*	**Caratteristica di protezione** *Protective feature*	**Sostanza** *Chemical*	**Livello** *Level*
EN 16523-1:2015	Permeazione *Permeation*	K - Idrossido di sodio 40% *Sodium hydroxide 40%*	6
EN 374-4:2013	Degradazione *Degradation*	K - Idrossido di sodio 40% *Sodium hydroxide 40%*	27.6 %

Il presente guanto fornisce protezione contro virus, batteri e funghi, secondo quanto indicato nella norma EN ISO 374-5:2016.
The glove gives protection against viruses, fungi and bacteria according to EN ISO 374-5:2016 standard.

Allegati al certificato di esame UE del tipo:
Annexes attached to EU type-examination certificate

Componente *Part*	**Rapporto di prova** *Test report*	**Emesso da** *Issued by*	**Data** *Date*
Guanto intero *Whole glove*	25-688.1	CIMAC	10/04/2025
	2020/0557-19-RP-2	CIMAC	25/03/2020
	21-4227-RP-3	CIMAC	10/02/2022

Il DPI soddisfa i requisiti essenziali di salute e sicurezza applicabili del Regolamento (UE) 2016/425.
The PPE type complies with the applicable essential health and safety requirements of Regulation (EU) 2016/425.

Data di emissione *Date of issue*	**Data di rinnovo** *Date of renewal*	**Data di revisione** *Date of revision*	**Data di scadenza** *Deadline*
10/06/2020	13/05/2025		13/05/2030

Marco Piccolini
Responsabile Tecnico *Technical Manager*

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TERMINI E CONDIZIONI *TERMS AND CONDITIONS*

I seguenti termini e condizioni si applicano in aggiunta alle condizioni generali di CIMAC allegate alla Proposta e Quotazione e a quelle indicate nel Regolamento per la valutazione della conformità UE REG01 nell'edizione corrente, disponibile sul sito internet www.cimac.it
Il fabbricante, titolare del presente certificato, è autorizzato a marcare il/i Dispositivo/i di Protezione Individuale (DPI) specificato/i nel presente certificato in conformità all'Allegato V (Modulo B) del Regolamento (UE) 2016/425 del Parlamento Europeo e del Consiglio del 9 marzo 2016, dopo che sia stata redatta da parte sua una dichiarazione di conformità UE del/i DPI.
Si noti che:

1. Se il/i DPI specificato/i nel presente certificato è/sono di categoria III, il certificato deve essere utilizzato solo in combinazione con una delle procedure di valutazione della conformità di cui all'art. 19 lettera c) del Regolamento (UE) 2016/425 (Modulo C2 o Modulo D).
2. La documentazione tecnica del fabbricante riporta tutti i dettagli dell'ambito di applicazione della certificazione e del/i DPI certificato/i.
3. Qualora esista una traduzione del presente certificato, la versione in lingua italiana sarà considerata il testo vincolante.
4. La certificazione è limitata alla produzione eseguita presso le sedi elencate nella documentazione tecnica del fabbricante.
5. Il/I DPI fabbricato/i in modo continuativo dovrà/dovranno essere coerente/i con il/i DPI certificato/i ed elencato/i nel presente certificato.
6. Il fabbricante dovrà comunicare a CIMAC eventuali modifiche al/ai DPI certificato/i o alla documentazione tecnica.
7. Se i risultati ottenuti durante le prove di tipo rientrano nei limiti di incertezza quando comparati al requisito di superamento della prova, alla classificazione o al livello di prestazione, il fabbricante ha la responsabilità di garantire che il controllo della produzione in fabbrica e le tolleranze di fabbricazione siano tali per cui il/i DPI immesso/i sul mercato soddisfa/no i requisiti, le classificazioni o i livelli di prestazione dichiarati.
8. Il presente certificato dovrà essere conservato unitamente alla relativa documentazione tecnica in un luogo sicuro dal fabbricante (o dal mandatario) indicato sul certificato stesso. Copia di questo certificato e di altra documentazione può essere richiesta da un rappresentante del governo di uno Stato membro UE.
9. Il presente certificato si riferisce soltanto al/ai DPI ed alla documentazione tecnica forniti al momento della procedura di valutazione della conformità ed è soggetto alla data di scadenza indicata.
10. CIMAC si riserva il diritto di revocare il presente certificato qualora sia accertato che una condizione di fabbricazione, progettazione, materiali o imballaggio è stata modificata e quindi non è più conforme ai requisiti del Regolamento (UE) 2016/245.
11. Il presente certificato può essere riprodotto solo a colori

The following terms and conditions apply in addition to CIMAC's general terms and conditions attached to the Proposal and Quotation and to those indicated in the Regulation for the assessment of EU conformity REG01 in the current edition, available on the website www.cimac.it
The manufacturer, holder of this certificate, is authorized to mark the Personal Protective Equipment (PPE) specified in this certificate in accordance with Annex V (Module B) of Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016, after an EU declaration of conformity of the PPE(s) was drawn up by him.
Please note:

1. *If the PPE(s) specified in this certificate is of category III, the certificate must be used only in combination with one of the conformity assessment procedures referred to in art. 19 letter c) of Regulation (EU) 2016/425 (Module C2 or Module D).*
2. *Full details of the scope of the certification and PPE(s) certified are contained within the manufacturer's technical documentation.*
3. *Where a translation of this certificate exists, the Italian language version shall be considered as the authoritative text.*
4. *Certification is limited to production undertaken at the sites listed in the manufacturer's technical documentation.*
5. *Ongoing manufactured product shall be consistent with the PPE(s) certified and listed on this certificate.*
6. *The manufacturer shall inform CIMAC of any changes to the certified PPE(s) or technical documentation.*
7. *Where results obtained during type testing are within the limits of uncertainty when compared to the pass requirement, classification or performance level, then it is the responsibility of the manufacturer to ensure that the factory production control and manufacturing tolerances are such that the PPE(s) placed on the market meets(meet) with the stated requirements, classifications or performance levels.*
8. *This certificate shall be kept together with the relevant technical documentation in a safe place by the manufacturer (or authorised representative) named on this certificate. Copy of this certificate and other documentation may be required by a representative of the EU member state government.*
9. *This certificate refers only to the PPE(s) and technical documentation provided at the time of the conformity assessment procedure and it is subject to the expiry date indicated.*
10. *CIMAC reserves the right to withdraw this certificate if it is found that a condition of the manufacture, design, materials or packaging have been changed and therefore no longer comply with the requirements of Regulation (EU) 2016/245.*
11. *This certificate can only be reproduced in color.*

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DNV·GL

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

APPENDIX TO EC CERTIFICATE

Appendix to Certificate no.:
10723-2017-CE-IND-NA-PS Rev. 3.0

Valid Until:
26 May 2024

This is an Appendix issued to EC Certificate issued for manufacturer:
KANAM LATEX INDUSTRIES PRIVATE LIMITED

originally issued in compliance with:
the Council Directive 93/42/EEC on Medical Devices, as amended

Based on assessment and/or audit performed, the following changes to the certification has been accepted as compliance with Council Directive 93/42/EEC on Medical Devices has been established.

A device already covered by the certification is placed on the market under an additional name or Identifier.

Products covered by this Certificate (replaces information on certificate):

10723-2017-CE-IND-NA-PS Rev. 3.0

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,	IIa

Place and date:
Høvik, 12 July 2021

For the issuing office:
DNV Product Assurance AS - Notified Body 2460
Veritasveien 3, 1363 Høvik, Norway

Hazem Tinawi
Technical Reviewer

	Sterigant+, Surgicare,Medix Gyna 480,Kings.	
	3. Surgical Gloves (Powder Free) Size:5.5 to 9.0 Brand: Comfort PF, Kaltex Plus,Surgicare Plus, Surgicare Plus DH, Surgicare Supreme, Comfort Powder-Free, Medibase, Bromed, IDA.	IIa
	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, **Nobafeel**	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**,Nobafeel**	IIa

	Gyn.	
	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, **Nobafeel sensitive.**	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 Gloves (Regular and Long cuff)	1.Non-Latex synthetic Surgical Gloves (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, **Nobafeel Syntex**	IIa
	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, **Nobaglove**	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

Appendix History -		
Revision	**Description**	**Issued Date**
0.0	Brand Addition In Bold	12 July 2021

APPENDIX TO EC CERTIFICATE

Certificate no.:
10723-2017-CE-IND-NA-PS Rev.3

Valid Until:
26 May 2024

This is an Appendix issued to EC Certificate issued for manufacturer:
KANAM LATEX INDUSTRIES PRIVATE LIMITED

originally issued in compliance with:
the Council Directive 93/42/EEC on Medical Devices, as amended

There are no changes to the certification to MDD, the basis for the certification nor the activities performed to maintain the certification.
The Accreditation with Norwegian Accreditation will cease from 01 Jan. 2022 and the accreditation mark has no validity.

Appendix History -		
Revision	**Description**	**Issued Date**
0	2252749 - Brand addition	06 February 2020
1	Admin change for removal of Norwegian Accreditation	16 December 2021

Place and date:
Høvik, 16 December 2021

For the issuing office:
DNV Product Assurance AS - Notified Body 2460
Veritasveien 3, 1363 Høvik, Norway

Yuan Li
Sr. Assessor

APPENDIX TO EC CERTIFICATE

Appendix to Certificate no.:
10723-2017-CE-IND-NA-PS Rev. 3.0

Valid Until:
26 May 2024

This is an Appendix issued to EC Certificate issued for manufacturer:
KANAM LATEX INDUSTRIES PRIVATE LIMITED

originally issued in compliance with:
the Council Directive 93/42/EEC on Medical Devices, as amended

Based on assessment performed, the following changes to the certification has been accepted as compliance with Council Directive 93/42/EEC on Medical Devices has been established.

A device already covered by the certification is placed on the market under an additional name or Identifier.

Products covered by this Certificate (replaces information on certificate):		
Product Description	**Product Name**	**Class**
1.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, **IMS, Juski, Surgicare Style 41**	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, **Juski**	IIa
	3.Surgical Gloves (Powder Free) Size: 5.5 to 9.0 Brand: Comfort PF, Kaltex Plus, Surgicare Plus, Surgicare Plus DH, Surgicare Supreme, Comfort Powder-Free, Medibase, Bromed, IDA	IIa
	4.Gynaecological Gloves (Powder Free)	IIa

Place and date:
Høvik, 28 December 2022

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

Hazem Tinawi
Technical Reviewer

	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	
	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, Nobafeel, **IDA, IMS, Juski, Surgicare Style 41 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, Nobafeel Gyn, **Juski**	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, Nobafeel sensitive	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, **Surgicare Ortho Style 41 PF**	IIa
2.Synthetic Surgical Gloves (Regular and Long cuff)	1.Non-Latex synthetic Surgical Gloves (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, Nobafeel Syntex	IIa
	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, **Juski**	Is
	2.Sterile Examination Gloves (Powder Free) Size: XS, S, M, L & XL Brand: Danglove, High Protection, Kaltex, Naturflex, HSO Polytex, Surgicare, Nobaglove, **Juski**	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

Appendix History -		
Revision	**Description**	**Issued Date**
0.0	Brand addition	12 July 2021
1.0	Admin Change for Removal of Norwegian Accreditation	16 December 2021
2.0	**Brand addition in bold**	28 December 2022

APPENDIX TO EC CERTIFICATE

Appendix to Certificate no.:
10723-2017-CE-IND-NA-PS Rev. 3.0

Valid Until:
26 May 2024

This is an Appendix issued to EC Certificate issued for manufacturer:
KANAM LATEX INDUSTRIES PRIVATE LIMITED

originally issued in compliance with:
the Council Directive 93/42/EEC on Medical Devices, as amended

Based on assessment performed, the following changes to the certification has been accepted as compliance with Council Directive 93/42/EEC on Medical Devices has been established.

EU Representative change has been accepted

EU Representative
Amstermed B.V., Saturnusstraat 46-62, Unit 032, 2132 HB Hoofddorp, The Netherlands

Appendix History -		
Revision	**Description**	**Issued Date**
0.0	Brand addition	12 July 2021
1.0	Admin Change for Removal of Norwegian Accreditation	16 December 2021
2.0	Brand addition in bold	28 December 2022
3.0	EAR Change	14 June 2023

Place and date:
Høvik, 14 June 2023

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

Hazem Tinawi
Technical Reviewer

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.