EC CERTIFICATION

PRODUCTION QUALITY ASSURANCE

Directive 93/42/EEC on Medical Devices, Annex V

We hereby declare that an examination of the under mentioned production quality assurance system has been carried out following the requirements of the Swedish national legislation LVFS 2003:11 to which the undersigned is subjected, transposing Annex V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation, and the result entitles the organization to use the CE 0413 marking on those products listed below.

Organization:

Tarun Enterprises

Main Site: 8/8, Strachy Road, Prayagraj (Allahabad), Uttar Pradesh, 211001, India

Product Category:

- Class I measuring devices
- Class I sterile devices

For further identification of the products covered, see the MDD product list/product schedule.

Certificate Number:
4130112475

Initial Certification Date:
6 April 2021

Certificate Valid from:
6 April 2021

Certificate Expiry Date:
26 May 2024

SWEDAC ACKREDITERING
Accred. no. 1003
Certification of Management Systems
ISO/IEC 17021-1

Certification Authority MDD
Intertek Semko AB, Kista, Sweden

6 April 2021

Signed Date

Intertek Semko AB
Box 1103, SE-164 22 Kista, Sweden
Telephone +46 8 750 00 00
medtechsweden@intertek.com

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

Intertek Semko AB is a Notified Body according to Directive 93/42/EEC on medical devices, with identification number 0413.

MDD – Product List

T103-3-SE-MDD

Products included in the certificate no: 4130112475
Issued to: **Tarun Enterprises**
8/8, Strachy Road
Prayagraj (Allahabad)
Uttar Pradesh, 211001
India

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Class I measuring devices					
	SCH 100 Schirmer Tear Test Strips	I(m+s)	Yes		6 April 2021
	SCH (MB) 100 Schirmer Tear Test Strips	I(m+s)	Yes		6 April 2021
	SCH (MB) 50 R&L Schirmer Tear Test Strips	I(m+s)	Yes		6 April 2021
Class I sterile devices					
	FL 10 FL Strips USP Higher Molecular 0.6 / 1 mg	I(s)	Yes		6 April 2021
	FL 20 FL Strips USP Higher Molecular 0.6 / 1 mg	I(s)	Yes		6 April 2021
	FL 50 FL Strips USP Higher Molecular 0.6 / 1 mg	I(s)	Yes		6 April 2021
	FL 100 FL Strips USP Higher Molecular 0.6 / 1 mg	I(s)	Yes		6 April 2021
	FL 300 FL Strips USP Higher Molecular 0.6 / 1 mg	I(s)	Yes		6 April 2021
	FL 500 FL Strips USP Higher Molecular 0.6 / 1 mg	I(s)	Yes		6 April 2021
	D5059 (Pediatric) Eye Shield	I(s)	Yes		6 April 2021
	D5060 Eye Shield	I(s)	Yes		6 April 2021
	D5061 Eye Shield	I(s)	Yes		6 April 2021
	D5062 Eye Shield	I(s)	Yes		6 April 2021

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Registered in Sweden: No SE556024059901, Registered office: As address

MDD – Product List

T103-3-SE-MDD

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
	OP 3035 Ophthalmic Drape	I(s)	Yes		6 April 2021
	OP 4035 Ophthalmic Drape	I(s)	Yes		6 April 2021
	OP 4055 Ophthalmic Drape	I(s)	Yes		6 April 2021
	OP 6060 Ophthalmic Drape	I(s)	Yes		6 April 2021
	OP 6040 Ophthalmic Drape	I(s)	Yes		6 April 2021
	OP 7070 Ophthalmic Drape	I(s)	Yes		6 April 2021
	OP 1080 Ophthalmic Drape	I(s)	Yes		6 April 2021
	OP 1010 Ophthalmic Drape	I(s)	Yes		6 April 2021
	OP 1215R Ophthalmic Drape	I(s)	Yes		6 April 2021
	OP 1512L Ophthalmic Drape	I(s)	Yes		6 April 2021
	OG101 Gown	I(s)	Yes		6 April 2021
	OG102 Gown	I(s)	Yes		6 April 2021
	OG103T Gown	I(s)	Yes		6 April 2021
	OG104T Gown	I(s)	Yes		6 April 2021
	OG105 Gown	I(s)	Yes		6 April 2021
	OG106 Gown	I(s)	Yes		6 April 2021
	OG107 Gown	I(s)	Yes		6 April 2021
	OG110 Gown	I(s)	Yes		6 April 2021
	OG111 Gown	I(s)	Yes		6 April 2021
	OG112 Gown	I(s)	Yes		6 April 2021
	OG113 Gown	I(s)	Yes		6 April 2021

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MDD – Product List

T103-3-SE-MDD

Date of Issue: 6 April 2021

Intertek Semko AB
Notified Body MDD

Certification Authority MDD

This product list is only valid together with the referenced, valid EC certificate.

The GMDN codes are assigned by the manufacturer and are only provided for convenience.

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MDD – Decision Report

Certificate No: 4130112475
Date: 6 April 2021
Handled by: Nina Fazil
E-mail: medtechsweden@intertek.com

Tarun Enterprises
Attn: Tarun Jaggi
8/8,Strachy Road
Prayagraj (Allahabad)
Uttar Pradesh, 211001
India

Purpose	Assessment to issue a new certificate for new client. Decision was made according to the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex V.
Activity	Stage 2 audit was perfomed 15-Feb-2021 – 20-Feb-2021 in Uttar Pradesh, India by Parvinder Singh.
Scope of assessment	Class I sterile devices & Class I measuring devices
Result	0 non conformities were noted during the audit.
Certificate Valid from	6 April 2021
Conclusions/Decisions	Referring to the above a Certificate of Conformance with the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex V will be issued. The Certificate is valid for products specified in the “MDD – Product List”.
Follow-up assessments	Follow-up assessments are going to be performed once a year.
Appeals	Any appeal against this decision will be processed by an appeals panel as Intertek. The appeal shall be submitted to Intertek Semko AB, PO-Box 1103, SE-164 22 Kista, Sweden.
Others	Any complaints, from customers and others, and corrective actions concerning your certified quality system shall be documented and retained. Upon request Intertek Semko has the right to review this documentation.

Intertek Semko AB
Notified Body MDD

Certification Authority MDD

OPTITECH®

TARUN ENTERPRISES

An EN ISO 13485:2016 COMPANY

Declaration of Certificate Validity

We, Tarun Enterprises, are a manufacturer of ophthalmic medical devices located at 8/8, Strachy Road, Prayagraj (Allahabad), with a plant at Shed No. E 20, NSIC Campus, Mirzapur Road, Naini, Prayagraj-211009, UP, India.

This declaration is to confirm that our CE certificate (No. 4130112475), which expired in May 2024, remains valid until we receive the official extension letter from Intertek.

We have recently undergone surveillance audits for both CE and ISO with the notified body Intertek. We are currently in the process of transitioning from MDD to EUMDR17, a procedure that requires considerable time. Consequently, Intertek has decided to grant us an extension on our MDD certificate.

Upon receiving the official extension letter from Intertek, we will promptly share it with you to ensure continued compliance and transparency.

Thank you for your understanding and continued support.

H.O. : 8/8, Strachy Road, Prayagraj, (Allahabad)-211001, U.P. India
Phone : +91 8176080204, e-mail: info@optitecheyecare.com
B.O. : A96/1, Second Floor, Phase II, Mayapuri Industrial Area, New Delhi-110064
Phone: +91 11 47070362, e-mail: delhi@optitecheyecare.com

"OPTITECH TARUN ENTERPRISES

Sertifikato galiojimo deklaracija

Mes, "Tarun Enterprises", esame oftalmologinių medicinos prietaisų gamintojas, įsikūręs adresu 8/8, Strachy Road, Prayagraj (Allahabad), su gamykla Shed No. E 20, NSIC Campus, Mirzapur Road, Naini, Prayagraj-211009, UP, Indija.

Šia deklaracija patvirtinama, kad mūsų CE sertifikatas (Nr. 4130112475), kurio galiojimas baigėsi 2024 m. gegužės mėn., galioja tol, kol iš "Intertek" gausime oficialų pratęsimo raštą.

Neseniai notifikuotoji įstaiga "Intertek" atliko CE ir ISO priežiūros auditą. Šiuo metu pereiname nuo MDD prie EUMDR17, o tai reikalauja daug laiko. Todėl "Intertek" nusprendė pratęsti MDD sertifikato galiojimą.

Gavę oficialų pratęsimo laišką iš "Intertek", nedelsdami pasidalinsime juo su jumis, kad užtikrintume nuolatinę atitiktį ir skaidrumą.

Dėkojame už supratimą ir nuolatinę paramą.

Data:-01-06-2024

AKIŲ PRIEŽIŪROS MEDICINOS PRIETAISAI ĮGŪDŽIŲ TOBULINIMAS

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