

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



Mikael Hagelin

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.



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

Product List for Certificate No: 4130112475
Date: 6 April 2021
Page 1 of 3

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

Product List for Certificate No: 4130112475

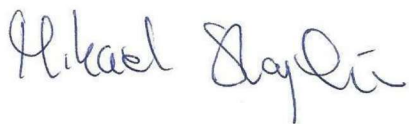
Date: 6 April 2021

Page 2 of 3

T103-3-SE-MDD

Date of Issue: 6 April 2021

Intertek Semko AB
Notified Body MDD



Mikael Hagelin
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.

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

Product List for Certificate No: 4130112475
Date: 6 April 2021
Page 3 of 3

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 performed 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

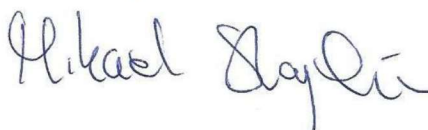
Conclusions/Decisions Referring to the above a Certificate of Conformance with the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex V will be issued. The Certificate is valid for products specified in the "MDD – Product List".

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



Mikael Hagelin
Certification Authority MDD

Vertimas iš anglų kalbos į lietuvių



Sertifikato numeris: 4130112475

Pirminio sertifikavimo data: 2021 m. Balandžio 6 d

Sertifikatas galioja nuo: 2021 m. Balandžio 6 d

Sertifikato galiojimo laikas iki: 2024 m. Gegužės 26 d

CE sertifikatas

GAMYBOS KOKYBĖS UŽTIKRINIMAS

Direktyvos 93/42 / EEB dėl medicinos prietaisų V priedas

Mes pareiškiame, kad minėtos gamybos kokybės užtikrinimo sistemos tyrimas buvo atliktas laikantis Švedijos nacionalinių įstatymų LVFS 2003: 11, kuriems taikomi žemiau pasirašę asmenys, reikalavimų, perkeliant Direktyvos 93/42 / EEB dėl medicinos prietaisų V priedą. Mes patvirtiname, kad produkcijos kokybės sistema atitinka atitinkamas pirmiau minėtų teisės aktų nuostatas, o rezultatas suteikia organizacijai teisę naudoti CE 0413 ženklą ant toliau išvardytų produktų.

Organizacija:

„Tarun Enterprises“

Pagrindinė svetainė: 8/8, Strachy Road, Prayagraj (Allahabad), Utar Pradešas, 211001, Indija

Produkto kategorija:

- I klasės matavimo prietaisai
- I klasės sterilūs įtaisai

Mikaelis Hagelinas

Sertifikavimo tarnyba MDD Intertek Semko AB,

Kista, Švedija

Pasirašymo data 2021 m. Balandžio 6 d

„Intertek Semko“ AB

Box 1103, SE-164 22 Kista, Švedija Telefonas +46 8 750 00 00 medtechsweden@intertek.com

Sertifikavimui reikia, kad organizacija išlaikytų savo sistemą laikydamasi šiame pažymėjime nurodytų taisyklių, leidžiančių reguliariai vertinti ir laikytis notifikuotosios įstaigos nustatytų reikalavimų.

„Intertek Semko AB“ yra notifikuotoji įstaiga, pagal Direktyvą 93/42 / EEB dėl medicinos prietaisų, kurios identifikavimo numeris yra 0413.

4130112475

Tarun Enterprises

8/8, Strachy Road Prayagraj (Allahabad)

Uttar Pradesh, 211001 India

MDD Produktų sąrašas

Širmerio testų juostelės, Fluoresceino juostelės, oftalmologinis užtiesalas, chalatas,
akių skydas

Išleidimo data: 2021 m. Balandžio 6 d. „Intertek Semko“ AB notifikuotosios įstaigos MDD

Šis produktų sąrašas galioja tik kartu su nurodytu galiojančiu EB sertifikatu.

„IntertekSemkoAB“ yra notifikuotoji įstaiga pagal Direktyvą 93/42 / EEB dėl medicinos prietaisų,
kurios identifikavimo numeris yra 0413