# 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

**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.

# 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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# 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

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.

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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.<br><br>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

Mikael Hagelin
Certification Authority MDD