*Anexa nr. 1*
*La Procedurile administrative pentru notificarea dispozitivelor medicale care dețin marcajul CE*

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

**NOTIFICARE**
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. ____

Solicitantul Tetis International Co SRL, cu sediul str. Calea Orheiului 103/3, Chisinau,
(adresa)
tel./fax: (022) 44 50 65, e-mail farma@tetis.md,
solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

- Dispozitive medicale conform listei:

| Nr. | Modelul | Nr de catalog | Denumire |
|---|---|---|---|
| 1 | Pristeen | | Manuşi chirurgicale, sterile, din latex, fara pudra |
| 2 | Pristeen | | Manuşi chirurgicale, sterile, din latex, cu pudra |

Se anexează următoarele acte:
a) declarația de conformitate CE emisă de producător pentru dispozitivul medical fabricat;
b) certificatul de conformitate CE valabil pentru dispozitivele fabricate, după caz;
c) actul prin care producătorul își desemnează reprezentantul.

Data Semnătura _____

**Tabelul de recepționare a notificării**
(se completează de către Agenție în momentul depunerii notificării de către solicitant)

| | |
|---|---|
| Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului | |
| Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării) | |
| Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului | |
| Semnătura persoanei responsabile | |

Digitally signed by Dicusar Vladimir
Date: 2023.08.04 13:25:19 EEST
Reason: MoldSign Signature
Location: Moldova

*Anexa nr. 2*
*La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE*

Către Agenția Medicamentului și Dispozitive Medicale

**DECLARAŢIE PE PROPRIE RĂSPUNDERE**

Solicitant: Tetis International Co SRL, cu sediul str. Calea Orheiului 103/3, Chisinau,

declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivului medical:

- Dispozitive medicale conform listei:

| Nr. | Modelul | Nr de catalog | Denumire |
|---|---|---|---|
| 1 | Pristeen | | Manuşi chirurgicale, sterile, din latex, fara pudra |
| 2 | Pristeen | | Manuşi chirurgicale, sterile, din latex, cu pudra |

**Sunt autentice și corespund realității.**

_____

*Numele, prenumele şi funcţia*

*Data* *Semnătura* _____

**Beta Healthcare Products Pvt. Ltd**
Manufactures of NR Latex Surgical & Examination Gloves
Adm. Office : Plot No. 21B | Cochin Special Economic Zone | Kakkanad,
Kochi - 682 037 | Kerala | INDIA
Phone : +91 484 2413389 | +91 484 2413390 | 2413341
Email : betahealthcarepurchase@gmail.com | Web : www.betahealthcare.com

Beta
Healthcare Products Pvt. Ltd.

## POWER OF ATTORNEY

Hereby we, **M/s Beta Healthcare Products Pvt. Ltd.** , whose registered office is at Plot No. 21B, Cochin Special Economic Zone, Kakkanad, Cochin, EranakulamKakkanad, Ernakulam, Kerala (India) - 682037 hereinafter referred to as **Manufacturer of Sterile Surgical Gloves** hereby authorizes the company **Tetis International Co SRL** (fiscal code 1003600043595) with registered office at Str. Calea Orheiului, 103/36, Chisinau, MD2020, Moldova, hereinafter referred to as ***"Authorized Manufacturer's Representative":***

- to represent interests of our company in all necessary state bodies and institutions for testing, registration and certification of medical equipment produced by MANUFACTURER;
- to carry out the discussions relating to testing and registration of medical equipment produced by MANUFACTURER;
- to submit all necessary documents to state bodies and institutions;
- to introduce amendments and addendum inserts into documents, to give explanations, to submit additional information;
- to obtain all necessary documents under MANUFACTURER's name;
- to receive the Registration Certificates (electronic of hard copies on paper) under MANUFACTURER's name.

This Power of Attorney is valid for 3 years.

Date: 28-07-2023

Name**: Boney Moolayil**

Designation: **Director**

Signature

BETA HEALTHCARE PRODUCTS PVT. LTD.
PLOT NO:21B
CSEZ
KAKKANAD
COCHIN-37

# EU Quality Management System Certificate

Certificate no.:
10000515641-PA-NoMA-IND

Initial certification date:
26 November 2022

Valid Until:
25 November 2027

This is to certify that the quality system of

## Beta Healthcare Products Private Limited

Plot No. 21B, Cochin Special Economic Zone,
Kakkanad,
Kochi – 682 037,
Kerala,
India

SRN: IN-MF-000019439

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

Sterile Latex Surgical Gloves Powdered and Powder Free and Sterile Latex Examination Gloves Powdered and Powder Free

Has been assessed and found to comply with respect to:

**The conformity assessment procedure described in Annex IX, (Chapter I) of Regulation (EU) 2017/745 on Medical Devices**

Place and date:
**Høvik, 26 November 2022**

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

**Palani Damodharan**
Management Representative

## Jurisdiction

Application of Regulation 2017/745 on medical devices, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

| Revision | Description | Report No. | Issue Date |
|---|---|---|---|
| 0.0 | Original Certificate | 2638819 | 26 November 2022 |

Products covered by this Certificate:

| Product Description (and intended purpose for class IIb) | Product Name | Class* |
|---|---|---|
| Sterile Latex Examination Gloves Powdered | **Size:** S, M, L, XL<br>**Brand:**<br>Hanzon<br>Eurotex examen P | **Is** |
| Sterile Latex Examination Gloves Powder free | **Size:** S, M, L, XL<br>**Brand:**<br>HanzOn, EurotexExamen SP, EurotexExamen SP emballage Unitaire | **Is** |
| Sterile Latex Surgical Gloves Powdered | **Size:** 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5,9.0<br>**Brand:**<br>Pristeen, Pristeen++, Perfekto, Protezione & Hospicare | **IIa** |
| Sterile Latex Surgical Gloves Powder free | **Size:** 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5,9.0<br>**Brand:**<br>Pristeen, Pristeen++, Perfekto, Protezione, Hospicare, Gant d’intervention chirurgicale SP Bordroule, Intervention Borddroit SP | **IIa** |

* Class III and class IIb devices referred to in the second subparagraph of Article 52(4): Technical documentation assessment is covered by a separate EU Technical Documentation Assessment Certificate No.: NA

The complete list of devices is filed with the Notified Body

## Sites covered by this certificate

| Site Name | Address |
|---|---|
| Site 1<br>Beta Healthcare Products Private Limited. | Plot No. 21B, Cochin Special Economic Zone, Kakkanad, Kochi – 682 037, Kerala,<br>India |
| Site 2<br>Greenband Foods (India) Private Limited. | Plot No. 39A, Cochin Special Economic Zone, Kakkanad, Kochi-682 037, Kerala, India |

| EU Representative |
|---|
| **Amstermed B.V**<br>Saturnusstraat 46-62,<br>Unit 032, 2132 HB Hoofddorp,<br>The Netherlands<br>www.amstermed.nl |

## 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 the Notified Body of any intended updating of the quality system and the Notified Body 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. Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.
- For the class III devices covered this certificate is dependent on the continued validity of the EU Technical Documentation Assessment Certificate, covering the devices.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window

## Specific conditions - Class I devices, Systems and Procedure Packs:

- For class I device being placed on the market in a sterile condition, Class I devices with a measurement function and class I devices being reusable surgical instruments covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 52(7) of the regulation.
- For system and procedure packs being placed on the market in a sterile condition, covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 22(3) of the regulation.

## Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EU declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

| | Sterile Latex Surgical Gloves- Powder Free<br>EC Declaration of Conformity |
|---|---|

| Doc. No. | Issue No. | Issue Date | Rev. No. | Revision Date |
|---|---|---|---|---|
| BHPL/EUDOC/LSGPF | 01 | 18.12.2021 | 00 | 18.12.2021 |

| | |
|---|---|
| Registered Office: | Name: Beta Healthcare Products Pvt. Ltd.<br>Address: Plot No.21B, Cochin Special Economic Zone, Kakkanad, Kochi-682 037, Kerala, India.<br>Tel: +91-484 2413340<br>Fax: +91- 2413341<br>Website: www.betahealthcare.com<br>SRN: IN-MF-000019439 |
| European Representative: | Name: Amstermed B.V<br>Address: Saturnusstraat 46-62, Unit 032, 2132 HB Hoofddorp, The Netherlands.<br>Phone: +31 23 5656337<br>Email: info@amstermed.nl<br>Website: www.amstermed.nl<br>SRN: NL-AR-000001971 |
| Device Name: | Sterile Latex Surgical Gloves Powder free |
| Brand Name: | Pristeen, Pristeen++, Perfekto, Protezione, Hospicare, Gant d'intervention, Intervention |
| Device Classification: | Class IIa, Rule 06 as per Annex VIII of MDR 2017/745 |
| EMDN Code: | T01010102 – Surgical Gloves, Latex, Non-Powdered |
| MDA/MDN Code: | MDN 1214 |
| MDS & MDT code(s): | MDS 1005, MDT 2004, MDT 2011 |
| Sterilization Method: | EO and Gamma Sterilization |
| Batch Number: | E.g. 2110D/08 |
| Conformity Assessment Route: | Annex IX |
| Declaration: | We hereby under our sole responsibility declare that the above-mentioned product meets the provisions of the Medical Device Regulation EU 2017/745, applicable harmonized standards, and as transposed into national laws. All supporting documentation is retained under the premises of the manufacturer. |
| Standards Applied: | **Harmonized Standards:**<br>EN ISO 13485: 2016/AC:2018, EN ISO 14971: 2019, EN 1041: 2008+A1:2013, EN ISO 15223-1:2016, EN 62366-1: 2015+AC:2015+AC:2016+A1:2020, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-7: 2008/AC:2009, EN ISO 10993-11:2018, EN ISO 10993-17:2009, EN ISO 11135: 2014+A1:2019, EN ISO 11138-2:2017, EN ISO 11737-1:2018, EN ISO 11737-2:2020, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009 |

BETA HEALTHCARE PRODUCTS PVT. LTD. PLOT NO:21B CSEZ KAKKANAD COCHIN-37

| | |
|---|---|
| Beta | **Sterile Latex Surgical Gloves- Powder Free**<br>**EC Declaration of Conformity** |

| Doc. No. | Issue No. | Issue Date | Rev. No. | Revision Date |
|---|---|---|---|---|
| BHPL/EUDOC/LSGPF | 01 | 18.12.2021 | 00 | 18.12.2021 |

| | |
|---|---|
| | **Other Standards:**<br>ISO 13485:2016, ISO 14971:2019, ISO 15223-1:2021, IEC 62366-1: 2015/AMD 1:2020, ISO 10993-1:2018, ISO 10993-5: 2009/AMD 1:2019, ISO 10993-7: 2008/AMD 1:2019+COR 1:2019, ISO 10993-10:2010, ISO 10993-11:2017, ISO 10993-10:2010, ISO 10993-11:2017, ISO 11135: 2014/AMD 1:2018, ISO 11737-1: 2018/AMD 1:2021, ISO 11737-2:2019, ISO 11607-1: 2019/CD AMD 1, ISO 11607-2: 2019/CD AMD 1, ASTM D3577:2019, ASTM D4169:2016, ASTM F1980-16:2016, ASTM D 6124-06:2017,ASTM D 3767-03:2020, ASTM D4332-14:2014, IS 13422:1992, ISO 10282:2014<br><br>**Guidelines:**<br>MEDDEV 2.7.1 Rev. 4: June 2016, MEDDEV 2.5/5 Rev. 3: February 1998, MEDDEV 2.12-1 Rev. 8: January 2013, MEDDEV 2.12/2 Rev. 2: January 2012, NB-MED 2.12/Rec. 1: July 2019, MEDDEV 2.5/9 Rev.1: Feb 2004, MDCG 2020-5:2020, MDCG 2020-6:2020, MDCG 2018-1 Rev.40 April 2021:, MDCG 2020-7:April 2020, MDCG 2020-8: April 2020 |
| | |
| Notified Body: | Name: DNV Product Assurance AS<br>Address: Veritasveien 3, 1363 Høvik, Norway<br>Website: www.dnv.com<br>Notified Body No.: 2460 |
| | |
| EC Certificate(s): | 10909-2017-CE-IND-NA-PS Rev.1 |
| | |
| Place & Date of Issue: | Kochi, Kerala, India &18.12.2021 |
| | |
| Signature:<br>(Name & Designation) | 18.12.2021<br>Srinivasan.S<br>General Manager & MR<br>BETA HEALTHCARE PRODUCTS PVT. LTD. PLOT NO:21B CSEZ KAKKANAD COCHIN-37 |

| | |
|---|---|
| Beta | **Sterile Latex Surgical Gloves- Powdered**<br>**EC Declaration of Conformity** |

| Doc. No. | Issue No. | Issue Date | Rev. No. | Revision Date |
|---|---|---|---|---|
| **BHPL/EUDOC/LSGPP** | **01** | **18.12.2021** | **00** | **18.12.2021** |

| | |
|---|---|
| Registered Office: | Name: Beta Healthcare Products Pvt. Ltd.<br>Address: Plot No.21B, Cochin Special Economic Zone,<br>Kakkanad, Kochi-682 037, Kerala, India.<br>Tel: +91-484 2413340<br>Fax: +91- 2413341<br>Website: www.betahealthcare.com<br>SRN: IN-MF-000019439 |
| European Representative: | Name: Amstermed B.V<br>Address:Saturnusstraat 46-62, Unit 032, 2132 HB Hoofddorp,<br>The Netherlands.<br>Phone:+31 23 5656337<br>Email:info@amstermed.nl<br>Website:www.amstermed.nl<br>SRN: NL-AR-000001971 |
| Device Name: | Sterile Latex Surgical Gloves Powdered |
| Brand Name: | Pristeen, Pristeen++, Perfekto, Protezione, Hospicare |
| Device Classification: | Class IIa, Rule 06 as per Annex VIII of MDR 2017/745 |
| EMDN Code: | T01010101 – Surgical Gloves, Latex, Powdered |
| MDA/MDN Code: | MDN 1214 |
| MDS & MDT code(s): | MDS 1005, MDT 2004, MDT 2011 |
| Sterilization Method: | EO and Gamma Sterilization |
| Batch Number: | E.g. 2110D/08 |
| Conformity Assessment Route: | Annex IX |
| Declaration: | We hereby under our sole responsibility declare that the above-mentioned product meets the provisions of the Medical Device Regulation EU 2017/745, applicable harmonized standards, and as transposed into national laws. All supporting documentation is retained under the premises of the manufacturer. |
| Standards Applied: | **Harmonized Standards:**<br>EN ISO 13485: 2016/AC:2018, EN ISO 14971: 2019, EN 1041: 2008+A1:2013, EN ISO 15223-1:2016, EN 62366-1: 2015+AC:2015+ AC:2016+A1:2020, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-7: 2008/AC:2009, EN ISO 10993-11:2018, EN ISO 10993-17:2009, EN ISO 11135: 2014+A1:2019, EN ISO 11138-2:2017, EN ISO 11737-1:2018, EN ISO 11737-2:2020, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009 |

BETA HEALTHCARE PRODUCTS PVT. LTD. PLOT NO-21B CSEZ KAKKANAD COCHIN-37

| Beta | Sterile Latex Surgical Gloves- Powdered<br>EC Declaration of Conformity |
|---|---|

| Doc. No. | Issue No. | Issue Date | Rev. No. | Revision Date |
|---|---|---|---|---|
| BHPL/EUDOC/LSGPP | 01 | 18.12.2021 | 00 | 18.12.2021 |

| | |
|---|---|
| | **Other Standards:**<br>ISO 13485:2016, ISO 14971:2019, ISO 15223-1:2021, IEC 62366-1: 2015/AMD 1:2020, ISO 10993-1:2018, ISO 10993-5: 2009/AMD 1:2019, ISO 10993-7: 2008/AMD 1:2019+COR 1:2019, ISO 10993-10:2010, ISO 10993-11:2017, ISO 10993-10:2010, ISO 10993-11:2017, ISO 11135: 2014/AMD 1: 2018, ISO 11737-1: 2018/AMD 1: 2021, ISO 11737-2:2019, ISO 11607-1: 2019/CD AMD 1, ISO 11607-2: 2019/CD AMD 1, ASTM D3577:2019, ASTM D4169:2016, ASTM F1980-16:2016, ASTM D 6124-06:2017, ASTM D 3767-03:2020, ASTM D4332-14:2014, IS 13422:1992, ISO 10282:2014<br><br>**Guidelines:**<br>MEDDEV 2.7.1 Rev. 4: June 2016, MEDDEV 2.5/5 Rev. 3: February 1998, MEDDEV 2.12-1 Rev. 8: January 2013, MEDDEV 2.12/2 Rev. 2: January 2012, NB-MED 2.12/Rec. 1: July 2019, MEDDEV 2.5/9 Rev.1: Feb 2004, MDCG 2020-5:2020, MDCG 2020-6:2020, MDCG 2018-1 Rev.40 April 2021:, MDCG 2020-7: April 2020, MDCG 2020-8: April 2020 |
| | |
| Notified Body: | Name: DNV Product Assurance AS<br>Address:Veritasveien 3, 1363 Høvik, Norway<br>Website:www.dnv.com<br>Notified Body No.:2460 |
| | |
| EC Certificate(s): | 10909-2017-CE-IND-NA-PS Rev.1 |
| | |
| Place & Date of Issue: | Kochi, Kerala, India &18.12.2021 |
| | |
| Signature:<br>(Name & Designation) | 18/12/2021<br>Srinivasan. S<br>(General Manager & MR)<br>BETA HEALTHCARE PRODUCTS PVT. LTD. PLOT NO:21B CSEZ KAKKANAD COCHIN-37 |