TECHNICAL FILE
Face Mask “Medical” SB

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1. Manufacturer details

VICTORS 111 LTD
Pleven 5800
Municipality of Pleven
Republic of Bulgaria
Grenaderska str. 121
VAT:BG 205708425

2. Name of the product

Medical device:

Three-layer mask for single use up to 2 (two) hours with elastic loop for face with mouth and nose UMDNS - 12458. The mask is intended to limit the transmission of infectious agents by patient and personnel during non-surgical procedures and other medical facilities with similar requirements. The medical / surgical mask has a suitable microbial barrier and may also be effective in reducing the excretion of infectious agents from the nose and mouth by an asymptomatic carrier or patient in clinical trials. **Class I** – low risk product by application IX of MDD – the Directive 93/42/EIO of the Union from 14 June 1993 concerning the medical equipments.

3. Facilities involved in the making of the product:

Production base in Republic of Bulgaria:

- Municipality of Pleven, Region of Pleven, city of Pleven 5800 Grenaderska str. 121
- Municipality of Byala Slatina, Region of Vratsa, city of Byala Slatina 3200, Tarnavska str. 42

4. Declaration of conformity assessment procedure:

Before putting on the CE marking over the **medical device CLASS I,** the manufacturer has applied EC declaration of conformity according annex 6 of the Ordinance on the essential requirements and the procedures for assessing the compliance with the essential requirements of medical devices under Art. 2 par. 1 dot 3 from the Law of the medical devices accepted with decree 186 from 31.07.2007 issued in National Paper issue 65 from 10.08.2007 and has made EC Declaration of Conformity before releasing the device to the market.

EC Declaration of conformity is a procedure in which the manufacturer or his authorized representative assures and declares that the device in question meets the applicable requirements of the Ordinance.

The technical documentation and declaration of conformity drawn up by the manufacturer or his authorized representative shall be kept by him for at least 5 years.

5. Declaration of conformity with the requirements of the EU:

VICTORS 111, Ltd.

CE Certificate of Conformity

VICTORS 111, Ltd., hereby declares that testing has been completed and reports have been generated for:

Applicant: VICTORS 111, Ltd., EU VAT number: 205708425
Address: 121 Grenaderska str., Pleven, 5800, Bulgaria
Manufactuer: VICTORS 111, Ltd., EU VAT number: 205708425
Address: 121 Grenaderska str., Pleven, 5800, Bulgaria
Product: Single-use 3-ply medical face mask

And in accordance with the following applicable directives:

COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices

Standard: EN 14683:2019+AC:2019

Therefore, **VICTORS 111, Ltd.**, hereby acknowledges that the applicant may issue a DECLARATION of CONFORMITY and apply the CE marking in accordance with European Union Rules.

VICTORS 111 LTD
Bulgaria, Pleven 5800
Grenaderska str. 121
VAT: BG 205708425

Attestation by: /Hristina [illegible]

Date: 7 April 2020

6. Label and instructions for use

The use of a Class I medical device does not require special handling and handling instructions. It is intended for single personal use up to 2 / two / hours in order to limit the transmission of infectious agents by medical personnel to patients and vice versa during surgical procedures and other medical facilities with similar requirements. The product is suitable for microbial barrier. It may be effective in reducing the excretion of infectious agents from the nose and mouth by an asymptomatic carrier or patient in clinical trials.

The product information required is provided on the packaging and is included in the declaration of conformity.

The manufacturer considers that the device could be used completely safely by the intended user without the need for instructions for use.

7. Statement of the relevant regulatory requirements that the product meets

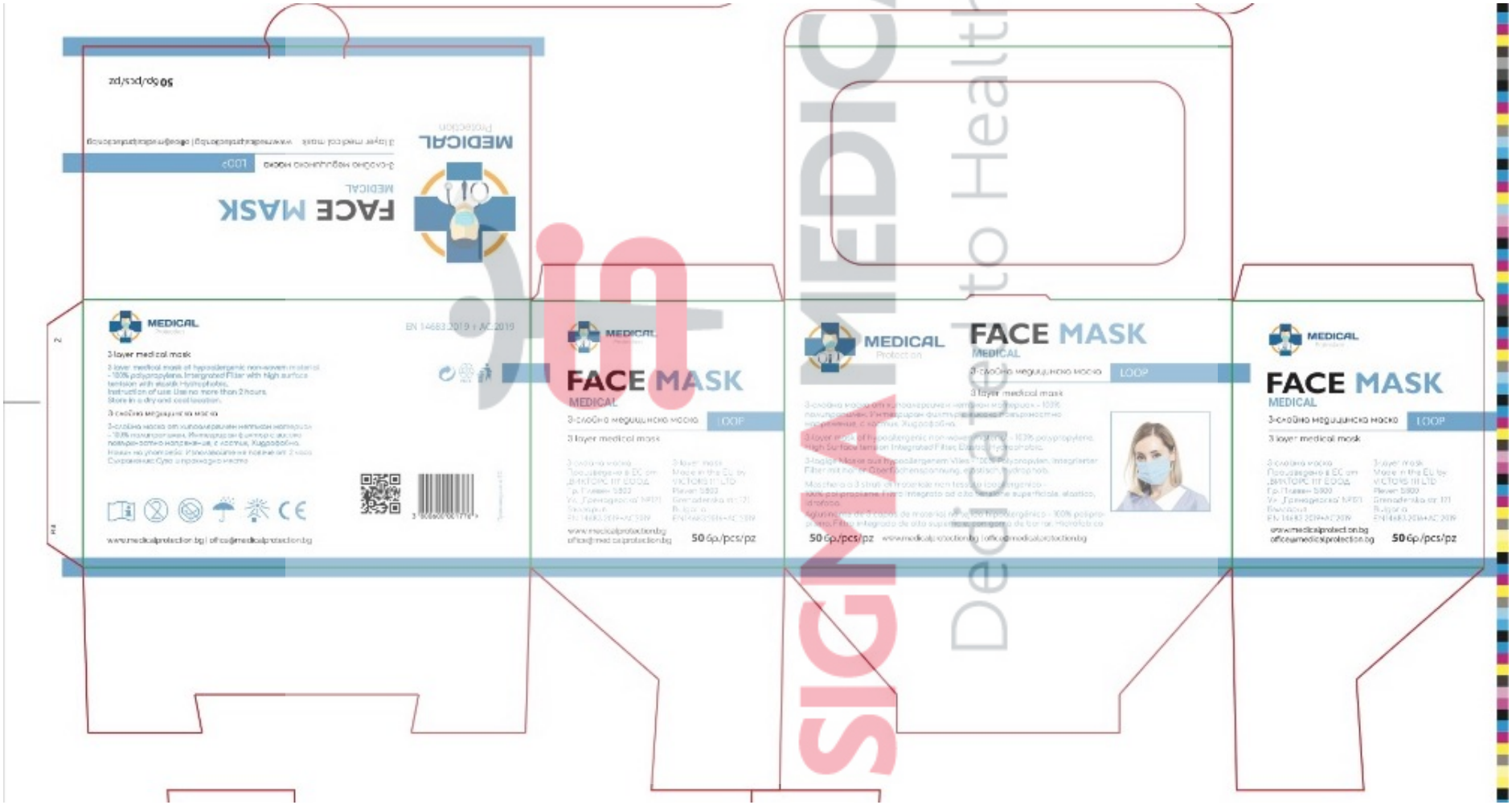
- The ordinance of Essential requirements and procedures for assessing compliance with the essential requirements of medical devices under Article 2, Paragraph 1, item 3 of the Medical Devices Act adopted with decree 186 from 31.07.2007 issued in Government Paper issue 65 from 10.08.2007

- Medical Devices act issued in Government paper issue 46 from 12.06.2007

- Directive 93/42/EIO of the Unity on 16 of June 1993 regarding the medical devices.

8. Design drawing and certificates of origin for the enclosed materials

Production code: **UMDNS 12458**
Applicable standard **BGS EN 14683:2019+AC:2019**


MEDICAL
FACE MASK
MEDICAL
3-слойна медицинска маска
LOOP
3 layer medical mask
EN 14683:2019 + AC:2019
50 бр./pcs./pz
www.medicalprotection.bg | office@medicalprotection.bg
SIGN MEDICAL
Dedicated to Health


MEDICAL
FACE MASK
SIGMAMEDICAL
Dedicated to Health

HOHENSTEIN Textile Testing Institute GmbH & Co. KG
Schlosssteige 1, 74357 Bönnigheim, Germany

OEKO-TEX®
INSPIRING CONFIDENCE

CERTIFICATE

The company

Extrapack OOD
Kozludzha Str. 1A
5000 Veliko Tarnovo, BULGARIA

OEKO-TEX®
CONFIDENCE IN TEXTILES
STANDARD 100
16.HBG.89637 HOHENSTEIN HTTI
Tested for harmful substances
www.oeko-tex.com/standard100

is granted authorisation according to STANDARD 100 by OEKO-TEX® to use the STANDARD 100 by OEKO-TEX® mark, based on our test report **19.0.83271**

for the following articles:

Non-woven fabric made of 100 % polypropylene in colours white, beige, light blue and black.

The results of the inspection made according to STANDARD 100 by OEKO-TEX®, Appendix 4, **product class I** have shown that the above mentioned goods meet the human-ecological requirements of the STANDARD 100 by OEKO-TEX® presently established in Appendix 4 for baby articles.

The certified articles fulfil requirements of Annex XVII of REACH (incl. the use of azo colourants, nickel release, etc.), the American requirement regarding total content of lead in children's articles (CPSIA; with the exception of accessories made from glass) and of the Chinese standard GB 18401:2010 (labelling requirements were not verified).

The holder of the certificate, who has issued a conformity declaration according to ISO 17050-1, is under an obligation to use the STANDARD 100 by OEKO-TEX® mark only in conjunction with products that conform with the sample initially tested. The conformity is verified by audits.

The certificate 16.HBG.89637 is valid until 30.09.2020

Boennigheim, 19.08.2019

Dipl.-Ing. (FH) Ivonne Schramm
Leiterin Zertifizierungsstelle OEKO-TEX®

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VAT: BG 205708425
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Issied:.....
/Hristina Valcheva – Manager/