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EC Declaration of Conformity

Document Number: **01/2020**
Manufacturer: **ZARENA AD**
Addresss: **ul. Nestor Abadzhiev, Plovdiv 4023, Bulgaria**

Product: **SURGICAL MASK**
Model: **FMN99**

Declares at its own risk that the above mentioned medical device complies with the applicable essential requirements set out in Annex I to the regulatory act described below and to regulatory technical documents when used as intended and in accordance with the safety instructions:

Document Number	Title ***Medical Devices: General***	Issue/Release Date
EU Directive 93/42/EEC	*Introduced into the national legislation with an ORDINANCE on the essential requirements and the procedures for assessment of the conformity with the essential requirements of medical decvices under Art. 2, para. 1, item 3 of the Medical Devices Act*	***14.06.1993 (last edited 11.10.2007)***

To achieve compliance, the requirements of the following harmonized standards are met:

Harmonized Standard	Title	Issue/Release Data
BDS EN 14683	*Surgical masks. Requirements and test methods (Medical face masks. Requirements and test methods)*	*2006 (2019+AC)*
BDS EN ISO 13485	*Medical devices - Quality management systems — Requirements for regulatory purposes (ISO 13485:2016)*	*2016*
BDS EN ISO 14971	*Medical devices — Application of risk management to medical devices (ISO 14971:2007, corrected version 2007-10-01)*	*2012*
BDS EN ISO 1041+A1 *BDS EN ISO 15223-1*	*Information supplied by the manufacturer of medical devices* *Medical devices — Symbols to be used with medical device labels, labelling and 2017 information to be supplied — Part 1: General requirements (ISO 15223-1:2016, corrected version 2017-03)*	*2017*

*Medical device – **Medical face mask (surgical mask)**, **UMDNS-12458** is classified in **Class I** in accordance with the rules set out in **ANNEX IX of DIRECTIVE 93/42 EEC**.*
*The declaration of conformity is issued in accordance with **ANNEX VII "EU DECLARATION OF CONFORMITY"** of Directive **93/42/EEC**, on the basis of the results of testing for compliance with the requirements of harmonized standard BDS EN 14683: 2019 + AC - **Test Report No 20.8.5.0232/ 29.04.2020** from Hohenstein Laboratories GmbH & Co. KG and Management System according to the requirements of BDS EN ISO 9001: 2015 - certificate **No 2011 8 C/11.03.2020.***

***Zarena AD, Markovo, district of Plovdiv** maintain data on the assurance and conformity assessment of the medical device (Technical dossier) in accordance with the requirements of Section 3 of ANNEX VII of Directive 93/42 / EEC.*

Plovdiv, 05.05.2020
(place and date of issuance)

sig. Yordanka Telkedzhieva
Manager

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