bluesail+
蓝帆医疗

Innovation & Quality

CH DECLARATION OF CONFORMITY

Manufacturer:	Zibo Blue Sail Innovation Co., Ltd No. 21 Qlngtlan Road, Qilu Chemlcal Industrlal Park, Zibo, Shandong 255414 China
CH Authorized Representative	SUNGO Technical Services GmbH Bahnhofstrasse 21 6300 Zug Switzerland
Device Name	Nitrile Powder Free Examination Gloves Refer to Attachment I for Trade Name
Intended Use	Nitrile Powder Free Examination Gloves are intended to be used to contribute to prevent cross contaminations in the framework of medical examinations and diagnostic / therapeutic procedures conducted under non - sterile conditions
Rule	1 and 5
Device Classification	Class I, according to Article 15 of Medical Devices Ordinance (MedDO)
Conformity Assessment Procedure	Annex II
Designated Standard	Refer to attachment II

WE, BLUE SAIL MEDICAL HEREWITH DECLARE THAT THE ABOVE MENTIONED DEVICE IS IN CONFORMITY WITH MEDICAL DEVICES ORDINANCE (MedDO) AND OTHER RELEVANT LEGISLATION THAT PROVIDES FOR THE ISSUANCE OF THIS DECLARATION OF CONFORMITY. THIS DECLARATION IS ISSUED UNDR THE SOLE RESPONSIBILITIES OF THE MANUFACTURER.

Start of CH Marking *Date: 28/11/2022*

Place and Date of Issue *Zibo, China*
20/06/2024

Signed on Behalf of BLUE SAI *Robin Liu*

ZIBO BLUE SAIL INNOVATION CO.,LTD

ATTACHMENT I

Product or Trade Name	Reference Number
Medbrun Nitrile Expert Light Blue	S: 14995 M: 14996 L: 14997 XL: 14998
Medbrun Nitrile Expert Light Blue 200	S: 37187 M: 37188 L: 37189 XL: 37190
Medbrun Nitrile Expert Black	S: 15277 M: 15278 L: 15279 XL: 15280
Medbrun Nitril Expert White	S: 18684 M: 18685 L: 18686 XL: 18687
Medbrun Nitril Expert Lavendel	S: 16768 M: 16770 L: 16771 XL: 16769

ATTACHMENT II

Standard	Title
ISO 9001:2015	Quality Management Systems – Requirements
EN ISO 13485:2016/A11:2021	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN 455-1:2020	Medical Gloves for Single Use Part 1: Requirements and Testing for Freedom from Holes
EN 455-2:2015	Medical Gloves for Single Use Part 2: Requirements and Testing for Physical Properties
EN 455-3:2015	Medical Gloves for Single Use Part 3: Requirements and Testing for Biological Evaluation
EN 455-4:2009	Medical Gloves for Single Use Part 4: Requirements and Testing for Shelf Life Determination
BS EN 1041:2008+A1:2013	Information Supplied by the Manufacturer of Medical Devices
BS EN ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
ISO 15223-1:2016	Medical Devices – Symbols to be Used with Medical Device Labels, Labelling and Information to be Supplied Part 1: General Requirements
ISO 10993-1:2018	Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process
ISO 10993-5:2009	Biological Evaluation of Medical Devices Part 5: Tests for In Vitro Cytotoxicity
ISO 10993-10:2021	Biological Evaluation of Medical Devices Part 10: Tests for Skin Sensitization
ISO 10993-11:2017	Biological Evaluation of Medical Devices Part 11: Tests for Systemic Toxicity
ISO 10993-18:2005	Biological Evaluation of Medical Devices Part 18: Chemical Characterization of Materials

ISO 10993-23:2021	Biological Evaluation of Medical Devices Part 23: Tests for Irritation
ISO 2859- 1:1999/Amd1:2011	Sampling Procedures for Inspection by Attributes Part 1: Sampling Schemes Indexed by Acceptance Quality Limit (AQL) for Lot-By-Lot Inspection
ASTM D4169-16	Standard Practice for Performance Testing of Shipping Containers and Systems