AZWAN INDUSTRIES
Khadim Ali Road, Islam Street, Noor Pura .51310 Sialkot. Pakistan.
Tell: 0092-300-8619519 Fax: 0092-52-3553750 Email: nadeemaftab24@gmail.com

EC DECLARATION OF CONFORMITY

ECDOC#031221/335-01 **Date: 03-12-2021**

MANUFACTURER:
AZWAN INDUSTRIES
Khadim Ali Road, Islam Street
Noor Pura. 51310 Sialkot-Pakistan

EC REP Authorized Representative in EU:
Yellow's Medical Instruments Gmbh
Max-Planck Str.3
12489 Berlin. Germany.

The EC declaration of conformity is issued for class I Medical Devices following the essential and applicable requirements as per Annex IV under EU MDR 2017/745.The declaration is issued under the sole responsibility of the manufacturer. Medical Devices attached in Annex A are in conformity with the MDR 2017/745 and relevant harmonized standards and the relevant parts of applicable standards of the European Union attached in Annex B, are applied where applicable and presumed to be in conformity with the requirements of ''Risk class I'' of medical devices in accordance with the rules set out in Annex VIII covered by those standards or parts thereof.

The products manufactured by Azwan Industries are mentioned in Annex A of this declaration. Products are manufactured in accordance with requirements of MDR 2017/745. The products declared are in compliance to applicable standards and or are harmonized by EU Medical Device Regulation 2017/745. The traceability of the devices covered by the EU declaration of conformity are in compliance where appropriate (Quality Management System) as well as its intended purpose.

We also declare that we will provide any document requested, technical documentation in its entirety and or in summary thereof. The product manufactured are Reusable (Non-Sterilized) and is class I as low risk product, lower risk products in line with Classification Rules Annex VIII. The product referred are developed with due care in lieu of technical documentation referred to in Annexes II and III.

To keep the technical documentation, the EU declaration of conformity and relevant certificates, including any amendments and supplements, issued in accordance with Article 56, available for a period of at least 05 years after the last device covered by the EU declaration of conformity has been placed on the market.

AZWAN INDUSTRIES
Partner

Authorized Signature: _____
Date: 03-12-2021
Name: Nadeem Aftab.
Azwan Industries. Partner.

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ANNEX A
Product List

We hereby declare that our products list has been classified as Class I Medical Devices inclusive of mentioned products variants is in Conformity with essential requirements , provision of Medical Device Regulation 2017/745 and Applicable regulatory requirements.

Sr. No.	Item Codes	Comed Cat REF.	Item Description & Size	Trade Name	Basic UDI-DI
1.	AI-91-4MCBL	29 080 00	Laryngoscope Macintosh Set 4 blades 1 handle in box Conventional Reusable.	Laryngoscopes	8964003079AI15101YR
2.	AI-5203	29 080 05	Laryngoscope Miller Blades size 1.		
3.	AI-5204	29 080 06	Laryngoscope Miller Blades size 2.		
4.	Ai-5903	29 080 11	Laryngoscope Bulbs size Large		
5.	AI-114-15	C1 114 15	Nail File 15cm	Nail File	8964003079AI114152H
6.	AI-115-14	C1 115 14	Nail Cutter 14cm	Nail Cutter	8964003079AI115142L
7.	AI-265-09	C2 265 09	Forceps Hartman Ear Polypus 9cm.	Forceps Hartman Ear	8964003079AI2560947
8.	AI-020-13	C3 020 13	Needle Holder Doyen 13cm.	Needle Holder Doyen	8964003079AI02013ZJ
9.	AI-100-02	C4 100 02	Buck Ear Curette 15cm, Dia 2mm.	Ear Curette	8964003079AI10002ZA
10.	AI-100-03	C4 100 03	Buck Ear Curette 15cm, Dia 3mm.		
11.	AI-105-03	C4 105 03	Ear Curette 15cm, Dia 3mm.		
12.	AI-105-04	C4 105 04	Ear Curette 15cm, Dia 4mm.		
13.	AI-150-13	C4 150 13	Scraper Vidal Sharp 13cm.	Scraper Nail	8964003079AI150132M

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ANNEX B

The products Mentioned in Annex A of this declaration are hereby declared in conformity with applicable Harmonized Standard mentioned as under;

STANDARDS	DESCRIPTONS
Medical Device Regulations (MDR).	Regulation EU 2017/745
Medical Devices Quality Management system Requirements for Regulatory purposes.	EN 1SO-13485:2016
Medical Devices Application of Risk management for medical devices	ISO 14971
Biological evaluation of medical devices-Part 1 : Evaluation & testing	ISO 10993-1
Biological evaluation of medical devices-Part 2 : Animal Welfare Requirements	ISO 10993-2
Biological evaluation of medical Devices-Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	EN ISO10993-3
Medical devices -- Symbols to be used with medical device labels, labelling, and information to be supplied - Part 2: Symbol	ISO 15223-2:2010
Graphical Symbols for Use in the Labeling of Medical Devices	ISO 15223-1
Medical device vigilance system	MEDDEV 2.12.1
Standard Specification for Stainless Steel Billet, Bar, and Wire for Medical Devices.	ASTM-F899: 2012
Medical device classification	EU MDR 2017/745 Annex VIII Article 51
Sterilization of Health care products	ISO 17665-1

AZWAN INDUSTRIES
Partner

Authorized Signature_____
Date: 03-12-2021
Name: Nadeem Aftab
Azwan Industries. Partner.