

EU Declaration of Conformity

Manufacturer: MEDISTAR INSTRUMENTS CO.					
Address: New Miana Pura East, Roras Road, Sialkot- 51310 Pakistan					
SRN Code: PK-MF-000025979					
Products List					
GIMA CODES	MEDISTAR CODES	INSTRUMENTS DESCRIPTION	Basic UDI-DI	RULE	CLASS
25835	701-07-50	All metal ear wax removing syringe 50cc	++G310GEWRSYRINGES04WY	05	1
25836	701-09-100	All metal ear wax removing syringe 100cc	++G310GEWRSYRINGES04WY	05	1
25837	701-14-150	All metal ear wax removing syringe 150cc	++G310GEWRSYRINGES04WY	05	1
25838	701-14-200	All metal ear wax removing syringe 200cc	++G310GEWRSYRINGES04WY	05	1

Intended Purpose: Device shall be used for ear wax removing purpose.	
Classification: Class I as per Regulation (EU) 2017/ 745 (MDR).	
Declaration:	
We, Medistar Instruments Co. herewith declare under our sole responsibility that the product(s) mentioned above meet the provisions of the Regulation (EU) 2017/ 745 (MDR). and categorized as Class 1 as per Regulation (EU) 2017/ 745 (MDR). File of technical documentation keep under the premises of the Manufacturer.	
Applicable Standards:	ISO 9001:2015: Quality Management Systems ISO 13485:2016: Medical Devices-Quality Management Systems-Requirements for Regulatory Purpose ISO 14971:2019: Medical Devices-Application of Risk Management to Medical Devices BS EN ISO 15223-1:2016: Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements cGMP: Medical Devices; Current Good Manufacturing Practice Medical Device Regulation (EU) 2017/ 745 (MDR): Council Regulation for Medical Devices ASTM B36 / B36M – 18: Standard Specification for Brass Plate, Sheet, Strip, And Rolled Bar. ISO 7153-1:2016: Surgical Instruments – Metallic Materials – Part 1: Stainless Steel
EU Representative:	
LORCAN & FYON B.V. EUROPALAAN, 40 3526KS UTRECHT, Netherlands.	
ECREP SRN Code: NL-AR-000039160	
Date of Issue: February 27, 2026	
Responsible Person: Sidra Jabeen	
Sign: 	



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