

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
25843	701-15-50	Metal glass ear wax removing syringe 50cc	++G310GMGEWRSYRINGESPY	05	1
25844	701-15-100	Metal glass ear wax removing syringe 100cc	++G310GMGEWRSYRINGESPY	05	1
25846	701-15-200	Metal glass ear wax removing syringe 200cc	++G310GMGEWRSYRINGESPY	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 ASTM-F899-20: Standard Specification for Stainless Steel Billet, Bar, and Wire for Surgical Instruments ASTM E438-92: Standard Specification for Glasses in Laboratory Apparatus				
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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