

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	RULE	CLASS
		Basic UDI-DI ++G310GEWRSYRINGES04WY		
25835	701-07-50	All metal ear wax removing syringe 50cc	05	1
25836	701-09-100	All metal ear wax removing syringe 100cc	05	1
25837	701-14-150	All metal ear wax removing syringe 150cc	05	1
25838	701-14-200	All metal ear wax removing syringe 200cc	05	1
Classification: Class I as per MDR 2017/745, Rule 05.				
Declaration:				
We, Medistar Instruments Co. herewith Declare under our sole responsibility that the product(s) mentioned above meet the provisions of the MDR 2017/745 and categorized as Class 1 as per MDR 2017/ 745. 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 ISO 17665-1:2006: Sterilization of Health Care Products - Moist Heat - Part 1: Requirements for the Development, Validation and Routine Control of a Sterilization Process for 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 MDR 2017/745: 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 ISO 10993-1:2018: Biological Evaluation of medical devices			
EU Representative:				
LORCAN & FYON B.V. EUROPALAAN, 40 3526KS UTRECHT, Netherlands.				
ECREP SRN Code: NL-AR-000039160				
Date of Issue: January 28, 2025				
Responsible Person: QA Manager				
Sign: 				