



United Poly Engineering Pvt. Ltd.

CIN No. U74899DL1980PTC010203

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ISSUE-01
REV-01

DECLARATION OF CONFORMITY

According to annex –IV section 1 to section 4 of the MDR 2017/745 of medical devices we:



United Poly Engineering Pvt. Ltd.
D-13/3, Okhla Industrial Area, Phase – II,
New Delhi-110020, India

Declare under our sole responsibility that the product:

DEVICE NAME		AS MENTIONED ON THE LABEL		SIZE	INTENDED USE/INTENDED PURPOSE OF THE DEVICE	UDI	CLASS & RULE	STERILE/ NON STERILE
CATEGORY	SUB-CATEGORY	MODEL	VARIANT					
Plastic Holloware	Trays	Kidney Tray / Emesis Basin	P-053	260 x 125 x 55 mm	Commonly used for collection, storage, transportation, sterilization of medical/surgical material / instruments/Specimen/Waste	8904042105490	1	Non Sterile
	Jug	Jug	P-103	Cap.500 ml	Commonly used for collection, storage, transportation, sterilization of medical/surgical material / instruments/Specimen/Waste	8904042105698	1	Non Sterile

LOT LOT/BATCH NO :--210105

MANUFACTURING DATE : -- 13.05.2021

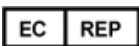
USED BY : --12.05.2026

Meets the provisions of the MDR2017/745 concerning medical devices which apply to them:

The MD is in Class I as per rule 1 of the risk based classification mentioned in Annexure VIII of the Medical Device Regulation MDR 2017/745, we have implemented quality management system. Following standards were used to prove the products conformity with the requirements of the MDR 2017/745:

Applicable Standards: EN ISO 14971: 2012, EN ISO 13485: 2016, EN ISO 15223: 2016 and other relevant product specification applied for the conformance.

Signatory established within the EU who has been empowered to enter into commitments on our behalf:



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For United Poly Engineering Pvt. Ltd.

(Signature)

Name: M.L. Verma
Position: Manager Quality Assurance
EMPLOYEE ID NO: 106
Place: New Delhi, India
Date: 08.06.2021



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