DIVINE MEDITECH PRIVATE LIMITED
EU DECLARATION OF CONFORMITY

Declaration Nu:	EU-DOC-12-2022
Declaration Date:	01/12/2022
Manufacturer:	Divine Meditech Private Limited G-197, Sector-63, Gautam Buddha Nagar Uttar Pradesh – 201301 India
SRN:	IN-MF-000029857
Product(s):	Digital Video Colposcope & variant with same BOM
BUDI-DI	

COLpro 222 DX-OZ View	222OZ	890615843222OZ46
COLpro 777-Full HD	777HD	890615843777HD5Q
COLpro222DX-OZ View Portable	222P	890615843222PAN

UDI-DI :	

COLpro 222 DX-OZ View	8906158430008
COLpro 777-Full HD	8906158430015
COLpro222DX-OZ View Portable	8906158430060

UDI-Pi:	Lot/ Serial No.
Product Code	COLpro 222 DX-OZ View , COLpro 777-Full HD, COLpro222DX-OZ View Portable
Intended Use:	Colposcope is used for examination of the tissues of the vagina, cervix and external genitalia by means of magnification to investigate abnormal cervical cytology or suspicious lesions of the lower female genital tract.
Applied Standards:	EN ISO 13485, EN ISO 14971
GMDN:	64925
EU Regulation and Legislation:	Regulation (EU) 2017/745
Risk Classification:	Class 1, Annex VIII – Chapter III - Rule 13
Conformity Route:	MDR Annex IV (Annex II and Annex III)
Declaration:	This EU Declaration of Conformity is issued under the sole responsibility of the Divine Meditech Private Limited, G-197, Sector-63, Gautam Buddha Nagar Uttar Pradesh – 201301 India. In the declaration, it is declared that the medical device in question is in compliance with the Regulation (EU) 2017/745

Divine Meditech Private Limited
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Declarant:	Sudhir Maithani R&D and Quality Director	
Place of Declaration	Uttar Pradesh, India	
Notified Body :	N/A	
EU Certificate:	N/A	
Design Certificate:	N/A	
Technical File and Retention Address:	DM/TCF/01 Keizersgracht 482, 1017 EG Amsterdam The Netherlands	
EU Authorized Representative:	Meddevices Lifesciences B.V. Address: Keizersgracht 482, 1017 EG Amsterdam The Netherlands SRN: NL-AR-000000594	