



DIVINE MEDITECH PRIVATE LIMITED
EU DECLARATION OF CONFORMITY

Declaration Nu:	EU-DOC-02-2023					
Declaration Date:	02/02/2023					
Manufacturer:	 Divine Meditech Private Limited G-197, Sector-63, Gautam Buddha Nagar Uttar Pradesh – 201301 India					
SRN:	IN-MF-000029857					
Product(s):	Patient Data Management Software					
BUDI-DI	<table border="1"><tr><td>DVC-IMS-019</td><td>019</td><td>890615843019HT</td></tr></table>			DVC-IMS-019	019	890615843019HT
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UDI-DI :	<table border="1"><tr><td>DVC-IMS-019</td><td>8906158430084</td></tr></table>			DVC-IMS-019	8906158430084	
DVC-IMS-019	8906158430084					
UDI-Pi:	Lot/ Serial No.					
Product Code	DVC-IMS-019					
Intended Use:	Colposcope Software is manage videos, images, clinical data and details of the patients and provide facility to store, edit, print the detailed reports.					
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 11					
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					

Release Date:	1.12.2021	Revision No.:	1	Revision Date:	1.12.2021	Page No.:	1/2
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Divine Meditech Private Limited

G-197, Sector-63, Gautam Buddha Nagar Uttar Pradesh – 201301 India

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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	