

EU DECLARATION OF CONFORMITY	
<b>Product Group</b>	Sterile Non-Absorbable Surgical Mesh
<b>Generic Name</b>	Polypropylene Mesh
<b>EMDN Code</b>	P900202
<b>Basic UDI-DI</b>	8903837P900202FY
<b>Brand Names</b>	TRULENE MESH, ALPHA LENE MESH, LINX REGULAR MESH, LINX LIGHT MESH, Q-CLOSE MESH, SURGISUT TRULENE MESH, IM -LENE MESH, LINX LAPRO MESH, B LENE MESH, RESORBA PP MESH, D-TEK POLYPROPYLENE MESH, TRULENE MACROPOR MESH, TRULENE SOFT MESH, TRULENE LAPARO MESH,
<b>Sizes</b>	Length: 1 to 30* Width 1 to 30* *All units are in centimetres.
<b>Indented Use:</b> Polypropylene mesh is intended for use in repair of abdominal wall hernias and abdominal wall deficiencies that require the addition of a reinforcing material to obtain the desired surgical result..	
<b>Registered Place of Business:</b>	Healthium Medtech Limited No. 472 D, 13 <sup>th</sup> Cross, 4 <sup>th</sup> Phase, Peenya Industrial Area, Bangalore – 560 058, Karnataka, India. SRN No.: IN-MF-000008421
<b>Address (office and Factory) of the Manufacturer:</b>	<b>Site 01:</b> Healthium Medtech Limited No. 472 D, 13th Cross, 4th Phase, Peenya Industrial Area, Bangalore Karnataka-560 058. India <b>Site 02:</b> Healthium Medtech Limited PLOT NO: 1605, PORTIA ROAD, SRI CITY, TIRUPATI DISTRICT, ANDHRA PRADESH– 517 646, INDIA
<b>E.U. Representative's name and address</b>	MED DEVICES LIFESCIENCES B.V. Keizersgracht 482 1017 EG Amsterdam, The Netherlands Email:info@meddevices.net Phone: +31-202254558 SRN No.:NL-AR-000000594
<b>Classification of the device:</b>	Polypropylene Mesh is classified as <b>Class III device</b> in accordance with Rule 8 of Annex VIII of the MDR 2017/745
<b>Notified Body's Address and Notified body number</b>	<b>3EC International a.s.</b> <b>Hranicna 18, 821 05 Bratislava,</b> <b>Slovak Republic.</b> <b>NB 2265</b>
<b>Certificate No.:</b>	<b>2022-MDR/QS-017</b>
<b>Document Reference No.</b>	<b>TD/CE/13</b>
<b>Applicable Standards</b>	EN ISO 13485:2016, ISO 14971:2019, ISO 9001: 2015, EN 556-1: 2001, EN 556-2: 2015, EN ISO 15223-1 : 2021 , EN ISO 20417-2021, EN ISO 11135-2014, ISO 10993-1:2018, ISO-11607-1 : 2019, ISO-11607-2 : 2019, ISO-11737-1: 2018, ISO 11737-2: 2019, EN ISO 14155:2020, ISO 14644-1:2015, EU.PHARMACOPEDIA 10th version, MEDDEV 2.7-1 rev 4, MEDDEV 2.12-1 rev 8, MEDDEV 2.12-2 rev 2.
<b>Quality Responsibility:</b> Healthium Medtech Limited., declares under sole responsibility for complying all the quality requirements of the product.	
<b>Declaration:</b> Healthium Medtech Limited, declares that Polypropylene Mesh meets the requirements of Quality as per USP specifications given in the monograph, Non-Absorbable Surgical Mesh and also complies with MDR 2017/745.	
The EU declaration of conformity is issued under the sole responsibility of the manufacturer.	



## Healthium Medtech Limited

(Formerly known as Healthium Medtech Private Limited)

Corporate Office: RMZ North Star, Cowrks, 12<sup>th</sup> Floor, Adjacent to RMZ Galleria Mall, Yelahanka, Bengaluru - 560 064, India

Registered Office: 472/D, 13<sup>th</sup> Cross, 4<sup>th</sup> Phase, Peenya Industrial Area, Bengaluru - 560 058, India

www.healthiummedtech.com | CIN : U03311KA1992PLC013831

Signature :	 
Name and Position	<b>Pankaj Dawar</b> PRRC
Date	<b>11-Nov-2022</b>
Place	<b>Bangalore</b>

## Healthium Medtech Limited

(Formerly known as Healthium Medtech Private Limited)

Corporate Office: RMZ North Star, Cowrks, 12<sup>th</sup> Floor, Adjacent to RMZ Galleria Mall, Yelahanka, Bengaluru - 560 064, India

Registered Office: 472/D, 13<sup>th</sup> Cross, 4<sup>th</sup> Phase, Peenya Industrial Area, Bengaluru - 560 058, India

[www.healthiummedtech.com](http://www.healthiummedtech.com) | CIN : U03311KA1992PLC013831