

| EU DECLARATION OF CONFORMITY   |  |
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| Product Group  | Sterile Synthetic Non-Absorbable Surgical Suture   |
| Generic Name   | Monofilament 316 LVM stainless steel   |
| EMDN Code  | H0102020101  |
| Basic UDI-DI   | 8903837H01020201012B   |
| Brand Names  | TRUSTEEL, ALPHA STEEL, Q-CLOSE STEEL, LINX STEEL, SURGISUT<br>TRUSTEEL, B-STEEL  |
| Sizes  | USP Sizes/EP Gauge – 1 / 4, 2/5, 3&4/6, 5/7, 6/8, 7/9  |
| <b>Indented Use:</b> Monofilament 316 LVM stainless steel suture is intended for use in abdominal wound closure, hernia repair, sternal closure and orthopaedic procedures including cerclage and tendon repair.   |  |
| Registered Place of Business:  | Healthium Medtech Limited<br>No. 472 D, 13 <sup>th</sup> Cross, 4 <sup>th</sup> Phase, Peenya Industrial Area,<br>Bangalore – 560 058, Karnataka, India.<br>SRN No.: IN-MF-000008421   |
| Address of the Manufacturing Unit :  | <b>Site 01:</b> Healthium Medtech Limited<br>No. 472 D, 13th Cross, 4th Phase, Peenya Industrial Area,<br>Bangalore Karnataka-560 058. India<br><b>Site 02:</b> Healthium Medtech Limited<br>PLOT NO: 1605, PORTIA ROAD, SRI CITY, TIRUPATI DISTRICT,<br>ANDHRA PRADESH– 517 646, INDIA  |
| E.U. Representative's name and address   | MED DEVICES LIFESCIENCES B.V.<br>Keizersgracht 482<br>1017 EG Amsterdam,<br>The Netherlands<br>Email:info@meddevices.net<br>Phone: +31-202254558<br>SRN No.:NL-AR-000000594  |
| Classification of the device:  | Monofilament 316 LVM stainless steel sutures are classified as<br><b>Class IIb device</b> in accordance with Rule 8 of Annex VIII of the MDR 2017/745  |
| Notified Body's Address and Notified body number   | <b>3EC International a.s.</b><br><b>Hranicna 18, 821 05 Bratislava,</b><br><b>Slovak Republic.</b><br><b>NB 2265</b>   |
| Certificate No.:   | <b>2022-MDR/QS-014</b>   |
| Document Reference No.   | <b>TD/CE/12</b>  |
| Applicable Standards   | EN ISO 13485:2016, ISO 14971:2019, ISO 9001: 2015, EN 556-1: 2001, EN 556-2: 2015, EN 868-7:2017, EN ISO 15223-1 : 2021 , 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.PHARMACOEIA 10th version, MEDDEV 2.7-1 rev 4, MEDDEV 2.12-1 rev 8, MEDDEV 2.12-2 rev 2. |
| <b>Quality Responsibility:</b><br>Healthium Medtech Limited., declares under sole responsibility for complying all the quality requirements of the product.  |  |
| <b>Declaration:</b> Healthium Medtech Limited, declares that Monofilament 316 LVM stainless steel sutures meets the requirements of Quality as per USP specifications given in the monograph, Non-Absorbable Surgical Suture, Synthetic and also complies with MDR 2017/745<br>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

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|-------------------|---|
| Signature :       |   |
| Name and Position | <b>Pankaj Dawar</b><br>PRRC   |
| Date              | <b>15-Nov-2022</b>  |
| Place             | <b>Bangalore</b>  |

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