

| EU DECLARATION OF CONFORMITY | |
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| Product Group | Sterile Synthetic Absorbable Surgical Suture |
| Generic Name | Braided and Coated Polyglycolic acid sutures |
| EMDN Code | H0101010201 |
| Basic UDI-DI | 8903837H0101010201ZH |
| Brand Names | TRUGLYDE, ANNCRYL, I GLYDE, LINX PGA, POLYGLYCOLIC ACID, U-GLYDE, PGA RESORBA, SURGISUT TRUGLYDE, B-GLYDE, TRUVET POLYGLYCOLIC ACID, IM-GLYDE, ESORB, UNODENT PGA, POGAL, N-CARE PGA, ALAN GLYDE |
| Sizes | USP Sizes/EP Gauge - 9-0/0.3, 8-0/0.4, 7-0/0.5, 6-0/0.7, 5-0/1, 4-0/1.5, 3-0/2, 2-0/3, 0/3.5, 1/4, 2/5 |
| Indented Use: Braided and Coated Polyglycolic acid sutures is intended for use in general soft tissue approximation and/or ligation, including use in plastic and ophthalmic procedures, but not for use in cardiovascular and neurological tissues. | |
| Registered Place of Business: | Healthium Medtech Limited No. 472 D, 13th Cross, 4th Phase, Peenya Industrial Area, Bangalore – 560 058, Karnataka, India. SRN No.: IN-MF-000008421 |
| Address of the Manufacturing Unit : | Site 01: Healthium Medtech Limited No. 472 D, 13th Cross, 4th Phase, Peenya Industrial Area, Bangalore Karnataka-560 058. India Site 02: Healthium Medtech Limited PLOT NO: 1605, PORTIA ROAD, SRI CITY, TIRUPATI DISTRICT, ANDHRA PRADESH– 517 646, INDIA |
| E.U. Representative's name and address | MED DEVICES LIFESCIENCES B.V. Keizersgracht 482 1017 EG Amsterdam, The Netherlands Email:info@meddevices.net Phone: +31-202254558 SRN No.:NL-AR-000000594 |
| Classification of the device: | Braided and Coated Polyglycolic acid sutures is classified as Class III device in accordance with Rule 8 of Annex VIII of the MDR 2017/745 |
| Notified Body's Address and Notified body number | 3EC International a.s. Hranicna 18, 821 05 Bratislava, Slovak Republic. NB 2265 |
| Certificate No.: | 2022-MDR/QS-005 |
| Document Reference No. | TD/CE/01 |
| Applicable Standards | 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.PHARMACOPEIA 10th version, MEDDEV 2.7-1 rev 4, MEDDEV 2.12-1 rev 8, MEDDEV 2.12-2 rev2. |
| Quality Responsibility: | Healthium Medtech Limited, declares under sole responsibility for complying all the quality requirements of the product. |
| Declaration: Healthium Medtech Limited, declares that Braided and Coated Polyglycolic acid sutures meets the requirements of Quality as per USP specifications given in the monograph, Absorbable Surgical Suture, Synthetic and also complies with MDR 2017/745. | |
| The EU declaration of conformity is issued under the sole responsibility of the manufacturer. | |

Healthium Medtech Limited

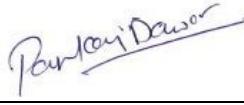
(Formerly known as Healthium Medtech Private Limited)

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

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

www.healthiummedtech.com | CIN : U03311KA1992PLC013831



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| Signature : |  |  |
| Name and Position | Pankaj Dawar PRRC | |
| Date | 11-Nov-2022 | |
| Place | Bangalore | |

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