


| EC DECLARATION OF CONFORMITY | |
|---|---|
| Product Group | Non Absorbable Surgical Suture |
| Model/Type | Non Absorbable Surgical Suture |
| GMDN Code | GMDN Code: 13910 |
| Brand Name | TRUSILK |
| Generic Name | Non Absorbable Silk Surgical Suture USP (Synthetic) Black Braided Silk |
| Sizes: 10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4 | |
| Indented Use: Trusilk is intended for use in soft tissue approximation and or ligation, including use in cardiovascular, ophthalmic and neurological tissues. | |
| Quality Responsibility: Healthium Medtech Pvt Ltd., Bangalore declares under Sole responsibility for complying all The quality requirements of the product. | |
| Address (office and Factory) of the Manufacturer: | Plot No.1600, R – 6 West, Sri City (SEZ), Cherivi Village, Irrugulam Post, Satyavedu Mandal, Chittoor Dist, Andhra Pradesh – 517588, India Ph: +91-80-41868000 – 41868030 |
| E.U. Representative's name and address | MED DEVICES LIFESCIENCES B.V. Kraijenhoffstraat 137 A, 1018RG Amsterdam, Netherlands Email: info@meddevices.net Phone: +31-202254558 |
| Classification of the device: | Trusilk is classified as Class III device in accordance with Rule 8 of Annex IX of the MDD 93/42/EEC. |
| Conformity Assessment Route | Annexure II, excluding (4) (Module H) of MDD 93/42/EEC Council directives as amended by 2007/47/EC |
| Notified Body's Address and | 3EC International a.s. Hranicna 18, 821 05 Bratislava, Slovak Republic. |
| Notified body number | NB 2265 |
| Certificate No.: | 2017-MDD/QS-055/B |
| Document Reference No. | TF/02/A |
| Applicable Standards | EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 15223-1 : 2016 , EN 1041:2008, EN 556-1: 2001, EN 556-2: 2015, ISO 11135: 2014, ISO 10993-1:2009, ISO 10993-5: 2009, EN ISO-10993-6 :2009, ISO 10993-7: 2008, ISO 10993-10: 2010, ISO 10993-13: 2010, EN ISO-10993-11 : 2009, EN ISO-11607-1 : 2009, EN ISO-11607-2 : 2006, EN ISO-11737-1: 2006, EN ISO 11737-2: 2009, EN ISO-14630 : 2012, ISO 14644-1:2015, EN 868-7:2017, MEDDEV 2.7-1 rev 4, MEDDEV 2.12-1 rev 8, MEDDEV 2.12-2 rev 2 |
| Declaration: Healthium Medtech Pvt. Ltd. Declares that Truslik meets the requirements of Quality as per USP specifications given in the monograph, Non Absorbable Surgical Suture, and also complies with the provisions of the council of Directives 93/42/EEC as amended by 2007/47/EC Directives for Medical devices. | |
| Signature : |  |
| Name and Position | Malesh. M Regulatory Affairs |
| Date | 27.03.2020 |
| Place | Bangalore |