EC DECLARATION OF CONFORMITY	
Product Group	Sterile Synthetic Absorbable Surgical Suture
Generic Name	Polydioxanone Suture
Brand Names	PDO RESORBA
Sizes	According to USP 2 (5 Metric), 1 (4 Metric), 0 (3.5 Metric), 2-0 (3 Metric) , 3-0 (2 Metric),4-0 (1.5 Metric), 5-0 (1 Metric), 6-0 (0.7 Metric), 7-0 (0.5 Metric), 8-0 (0.4 Metric) with or without needles
Indented Use: PDO RESORBA monofilament synthetic absorbable sutures are indicated for use in all types of soft tissue approximation, including use in ophthalmic surgery. PDO RESORBA sutures is not indicated in adult cardiovascular tissue, microsurgery and neural tissue. These sutures are particularly useful where the combination of an absorbable suture and extended wound support (up to six weeks) is desirable	
Address (office and Factory) of the Manufacturer:	No. 472 D, 13th Cross, 4th Phase, Peenya Industrial Area, 560 058 Bangalore, Karnataka, India Ph: +91-80-41868000 Fax: +91-80-41171056
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:	Polydioxanone Suture is classified as **Class III device** in accordance with with Rule 8 of Annex IX of the MDD 93/42/EEC.
Notified Body's Address and Notified body number	**3EC International a.s.** **Hranicna 18, 821 05 Bratislava,** **Slovak Republic.** **NB 2265**
CE Certificate & EC Design Examination No.:	**2020-MDD/QS-127 & 2020-MDD/DE-128**
Document Reference No.	**TF/CE/01**
Applicable Standards	ISO 13485:2016, ISO 14971:2019, EN ISO 15223-1 : 2021 , BS ISO 20417-2021, EN 556-1: 2001, EN 556-2: 2015, ISO 11135: 2014, ISO 10993-1:2018, EN ISO-11607-1 : 2019, EN ISO-11607-2 : 2019, EN ISO-11737-1: 2018, EN ISO 11737-2: 2019, 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 Limited Declares that Polydioxanone Suture meets the requirements of Quality as per USP specifications given in the monograph, Absorbable Surgical Suture, Synthetic 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	**Pankaj Dawar** Regulatory Affairs
Date	**24-Aug-2021**
Place	**Bangalore**