


EC DECLARATION OF CONFORMITY	
Product Group	Absorbable Hemostat
Generic Name	Oxidized regenerated cellulose
Brand Names	Clinical
Sizes	Knitted: 2 in x 3 in (5.1cm x 7.6cm), 2 in x 14 in (5.1cm x 35.5cm), 4 in x 8 in (10cm x 20cm), Fibrillar: 1 in x 2 in (2.5cm x 5.1cm) 2 in x 4 in (5.1cm x 10cm)
Intended Use: Absorbable hemostat is indicated for use in a variety of surgical settings to control hemostasis in situations where ligature or conventional procedures are either ineffective or impractical. These devices play an important role in controlling bleeding during surgery and in minimizing re-bleeding and oozing in the post-operative period.	
Registered Place of Business:	Healthium Medtech Limited No. 472 D, 13 th Cross, 4 th Phase, Peenya Industrial Area, Bangalore – 560 058, Karnataka, India. Ph: +91-80-41868000 Fax: +91-80-41171056
Address of the Manufacturing Unit:	Healthium Medtech Limited No. 472 D, 13 th Cross, 4 th Phase, Peenya Industrial Area, Bangalore – 560 058, Karnataka, India. Ph: +91-80-41868000 Fax: +91-80-41171056
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
Classification of the device:	Absorbable Hemostat Suture is classified as Class III device in accordance with Rule 8 of Annex IX of the MDD 93/42/EEC.
Conformity Assessment Route:	Clinical Conformity Assessment in accordance with Annex II excluding 4 of the directive MDD 93/42/EEC as amended.
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.:	2018-MDD/QS-039/B & 2018-MDD/DE-040/B
Document Reference No.	TF/CE/07
Applicable Standards	EN ISO 13485:2016, ISO 14971:2019, EN ISO 15223-1 : 2021, EN ISO 20417-2021, EN 556-1: 2001, EN 556-2: 2015, ISO 10993-1:2018, ISO11607-1 : 2019, ISO-11607-2 : 2019, EN ISO-11737-1: 2018, EN ISO 11737-2: 2019, ISO 14644-1:2015, MEDDEV 2.7-1 rev 4, MEDDEV 2.12-1 rev 8, MEDDEV 2.12-2 rev 2
Declaration: Healthium Medtech Limited, declares that Absorbable Hemostat meets the requirements of Quality as per in-house specifications 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	10-July-2023
Place	Bangalore

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

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