

EC DECLARATION OF CONFORMITY	
Product Group	Absorbable Hemostat
GMDN Code	38771
Brand Name	CLINICEL
Generic Name	Oxidized Regenerated Cellulose
Model/Type	Knitted & Fibrillar
Indented Use: Clinicel is indented for use in a variety of surgical settings to control hemostasis in situations where ligature or conventional procedures are either ineffective or impractical.	
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:	No. 472 D, 13 th Cross, 4 th Phase, Peenya Industrial Area, Bangalore – 560 058, 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:	Clinicel 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.:	2018-MDD/QS-039/A
Document Reference No.	TF/07
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 Clinicel 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	Malesh. M Regulatory Affairs
Date	27.03.2020
Place	Bangalore