DECLARATION OF CONFORMITY

Issued according to EC directive 93/42/EEC relating to Medical Devices

Manufacturer Name & Address	:	**AXIO BIOSOLUTIONS PRIVATE LIMITED**, Plot 18, Gujarat Pharma Techno Park, Sari Matoda, Sanand Taluka, Ahmedabad-382220, Gujarat, India. Phone: +91 8860786067 E-mail: info@axiobio.com
EC Representative	:	Emergo Europe B.V Prinsessegracht 20, 2514 AP The Hague, The Netherlands.
Product Category	:	Chitosan Wound Dressing
Brand Name	:	MaxioCel®, AxioCel
Sizes	:	1x2cm, 1x3cm, 2.5cm x 30cm, 5cm x 10cm, 10cm x 10cm, 15cm x 15cm, 20cm x 30cm, 45cm x 45cm, 2.5cm x 45cm, 8cm x 8cm, 12.5cm x 12.5cm, 17.5cm x 17.5cm, 25cm x 30cm, 8cm x 13cm, 10cm x 20cm, 10cm x 25cm, 10cm x 30cm, 19.8cm x 14cm, 20cm x 16.9cm, 24cm x 21.5cm, 7.6cm x 50cm, 7.6cm x 100cm, 7.6cm x 150cm, 7.6cm x 300cm.
Product Description	:	Maxiocel is a soft, sterile, single use absorbent microfiber wound dressing used for absorption of wound exudate and control of minor bleeding. It transforms into a cohesive gel matrix gel when in contact with wound exudate. Maxiocel helps maintain a moist environment for optimal wound healing and is easy to remove. It can be kept on the wound site for up to 7 days.
Class	:	Class III
GMDN No.	:	46854
Annexure No.	:	Annexure II
Notified Body	:	DNV GL Presafe AS (2460)
Applied Directive	:	The Directive 93/42/EEC on medical devices, conformity assessment according to Annexure II

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STANDARDS APPLICABLE

S.No	List of Standards
1	BS EN ISO 10993-5: 2009 - Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
2	BS EN ISO 11137-1: 2019 - Sterilization of health care products - Radiation - Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices
3	ISO 11607-1-2006 - Packaging For Terminally Sterilized Medical Devices - Part 1: Requirements For Materials, Sterile Barrier Systems And Packaging Systems
4	ISO 11607-2-2006 - Packaging For Terminally Sterilized Medical Devices - Part 2: Validation Requirements For Forming, Sealing And Assembly Processes
5	ISO 10993-1-2009 - Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process.
6	ISO 10993-10: 2010 - Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
7	ISO 10993-11: 2017 - Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
8	ISO 11137-2:2013 - Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
9	ISO 22442-1:2015 - Medical devices utilizing animal tissues and their derivatives — Part 1: Application of risk management
10	ISO 22442-2:2015 - Medical devices utilizing animal tissues and their derivatives — Part 2: Controls on sourcing, collection and handling
11	ASTM F1980-16 - Standard Test Method for Seal Strength of Flexible Barrier Materials

The company, Axio Biosolutions Private Limited, herewith declares that the above- mentioned product meets all applicable provisions of the Directive 93/42/EEC. The product is safe under prescribed and reasonably foreseeable conditions of storage and use.

The company has instituted and keeps up to date a systemic procedure to review experience gained from devices in the post-production phase and to implement appropriate means for the necessary corrective

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actions.

The company has implemented measures assuring that all products of the above-mentioned type are safe and fulfill essential requirements of the 93/42/EEC Directive.

If the device is modified without the agreement of the undersigned, this declaration becomes invalid in relation to the modified product.
The declaration is on the sole responsibility of Axio Biosolutions Private Limited.

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AXIO BIOSOLUTIONS PVT. LTD.
AXIO
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Leo Mavely, Director