

# EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

## MDR 788611 R000

**Manufacturer:** PolyNovo Biomaterials Pty Ltd

**Address:**

2/320 Lorimer Street  
Port Melbourne  
VIC 3207  
Australia

**Single Registration Number:** AU-MF-000009555

**EU Authorised Representative:** Emergo Europe B.V.

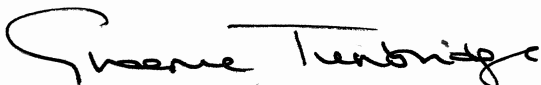
**Address:**

Westervoortsedijk 60  
6827 AT Arnhem  
The Netherlands

**Scope:** See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2024-02-15**

Current Issue Date: **2024-02-15**

Starting Validity Date: **2024-02-15**

Expiry Date: **2029-02-14**

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### Device Schedule:

#### Intended Purpose as per the Instructions for Use:

NovoSorb BTM is intended to temporise dermal injuries where the dermis has been decimated or lost, and to facilitate dermal repair by providing temporary wound closure and a scaffold for the generation of a neodermis.

**Risk Classification:** Class III Implantable

**Basic UDI-DI:** 0934915500BTM7G

Device Name	Model	Type (Codes as per (EU) 2017/2185)
NovoSorb BTM Biodegradable Temporising Matrix	BTM-0304 3 cm x 4 cm Pack size: 1	MDN 1104
NovoSorb BTM Biodegradable Temporising Matrix	BTM-0505 5 cm x 5 cm Pack size: 1	MDN 1104
NovoSorb BTM Biodegradable Temporising Matrix	BTM-0608 6 cm x 8 cm Pack size: 1	MDN 1104
NovoSorb BTM Biodegradable Temporising Matrix	BTM-1010 10 cm x 10 cm Pack size: 1	MDN 1104
NovoSorb BTM Biodegradable Temporising Matrix	BTM-1020 10 cm x 20 cm Pack size: 1	MDN 1104
NovoSorb BTM Biodegradable Temporising Matrix	BTM-2025 20 cm x 25 cm Pack size: 1	MDN 1104
NovoSorb BTM Biodegradable Temporising Matrix	BTM-2040 20 cm x 40 cm Pack size: 1	MDN 1104

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### Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from [Certificate.Verification@bsigroup.com](mailto:Certificate.Verification@bsigroup.com))

Date	Reference Number	Action
Current	3892923	Issued



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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.  
This certificate was issued electronically and is bound by the conditions of the contract.