

EU Technical Documentation Assessment Certificate

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

MDR 730031 R000

Manufacturer: Johnson & Johnson International

Address:

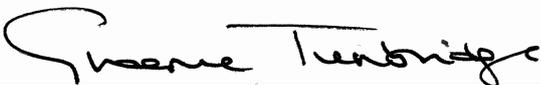
c/o European Logistics Centre
Leonardo Da Vincilaan 15
BE-1831 Diegem
Belgium

Single Registration Number: BE-MF-000008018

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 Global Regulatory & Quality

First Issue Date: **2024-03-21**

Current Issue Date: **2024-05-01**

Starting Validity Date: **2024-05-01**

Expiry Date: **2029-03-20**

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Device Schedule:

Intended Purpose as per the Instructions for Use:

VICRYL™ Mesh may be used wherever temporary wound or organ support is required, particularly in instances in which compliant and stretchable support is desired. VICRYL™ Mesh may be cut to the shape or size desired for each specific application.

| Device Name | Model | Type (Codes as per (EU) 2017/2185) | Risk Classification | Basic UDI-DI |
|--|-------------|------------------------------------|------------------------|-----------------|
| VICRYL Mesh Polyglactin 910 undyed knitted absorbable mesh | VICRYL Mesh | MDN 1104 | Class III, Implantable | 0705031a006835D |

Additional Information:

| Product Code | Product Description | Style | Units per Box |
|--------------|-------------------------------|-----------------|---------------|
| VM1208 | VICRYL Mesh 12 cm x 8 cm | Style 9 Fine | 3 |
| VM2515 | VICRYL Mesh 25 cm x 15 cm | Style 9 Fine | 3 |
| VM302 | VICRYL Mesh 3 cm x 2 cm | Style 9 Fine | 3 |
| VM3020 | VICRYL Mesh 28 cm x 18 cm | Style 9 Fine | 3 |
| VM605 | VICRYL Mesh 6 cm x 5 cm | Style 9 Fine | 3 |
| VM72 | VICRYL Mesh 13.5 cm x 11 cm | Style 12 Coarse | 1 |
| VM74 | VICRYL Mesh 26.5 cm x 21.5 cm | Style 12 Coarse | 1 |
| VM802 | VICRYL Mesh 8 cm x 2 cm | Style 9 Fine | 3 |

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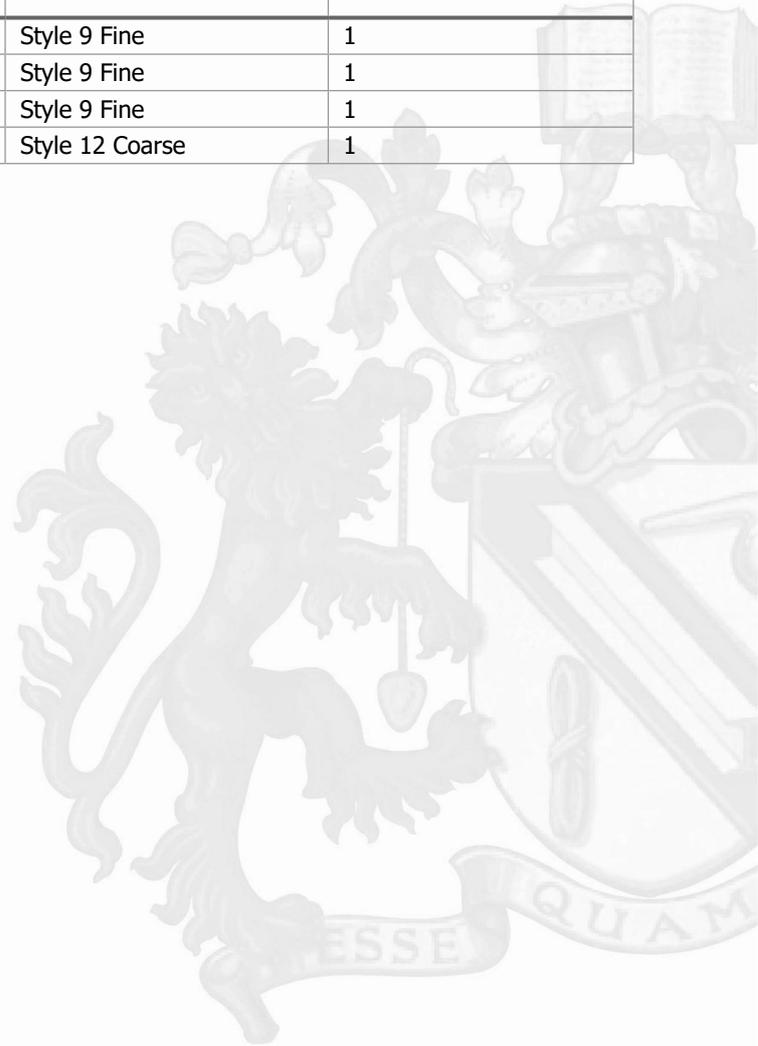
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| Product Code | Product Description | Style | Units per Box |
|--------------|-------------------------------|-----------------|---------------|
| VM94 | VICRYL Mesh 26.5 cm x 21.5 cm | Style 9 Fine | 1 |
| VM95 | VICRYL Mesh 26.5 cm x 34 cm | Style 9 Fine | 1 |
| VM96 | VICRYL Mesh 8.5 cm x 10.5 cm | Style 9 Fine | 1 |
| X579 | VICRYL Mesh 35 cm x 28 cm | Style 12 Coarse | 1 |



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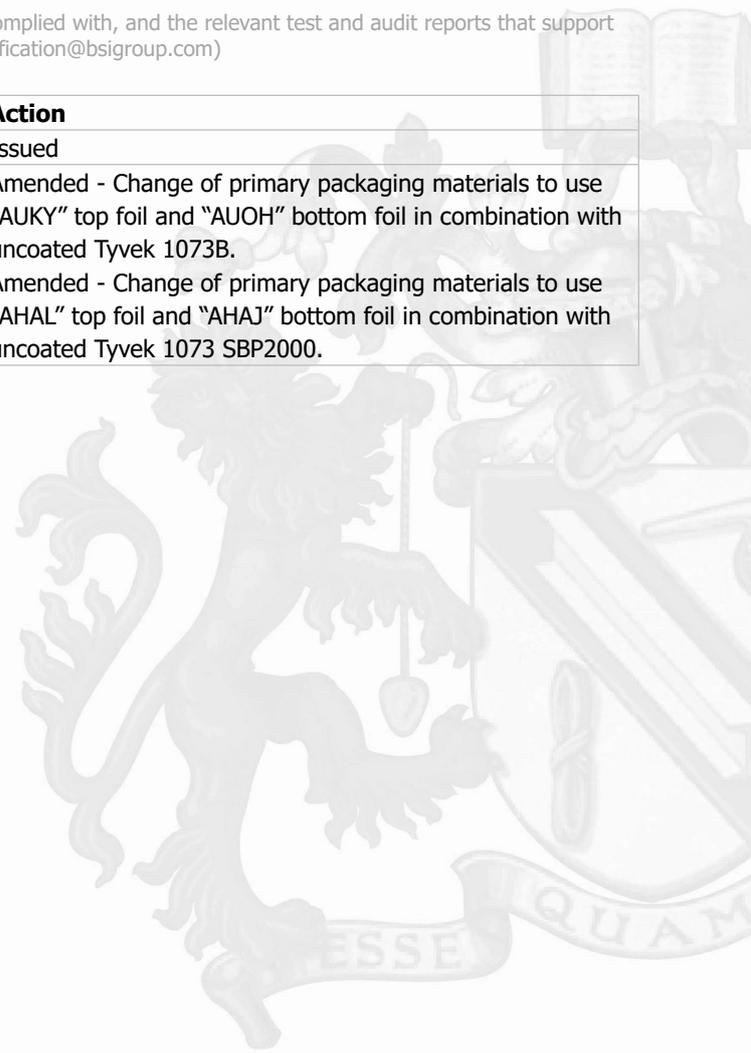
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Certificate History

(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)

| Date | Reference Number | Action |
|------------|------------------|---|
| 2024-03-21 | 3219920 | Issued |
| Current | 30163498 | Amended - Change of primary packaging materials to use "AUKY" top foil and "AUOH" bottom foil in combination with uncoated Tyvek 1073B. Amended - Change of primary packaging materials to use "AHAL" top foil and "AHAJ" bottom foil in combination with uncoated Tyvek 1073 SBP2000. |



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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.