

CE 0413

DECLARATION of CONFORMITY – DoC
in accordance with EN ISO/IEC 17050-1:2010

We the Manufacturer: American Surgical Company
45 Congress St.
Suite 153
Salem, MA 01970
USA

Authorized European Community Representative and
Location of Responsible Person: EU Authorized Representative
Emergo Europe
Westervoortsedijk 606827 At Arnhem The Netherlands

Declaration: We hereby declare that the herein mentioned devices comply with the
LVFS 2003:11 transposing European Medical Devices Directive
93/42/EEC and Article 120 of the European Medical Device
Regulations 2017/745.

Product Group: Neurosurgical Sponges
Product Family: Neurosurgical Sponges Product Families
Product Schedule: See attached

Classification: Class III Per Rule 7 of Annex IX of the Council Directive 93/42/EEC, as amended
per 2007/47/EC, concerning medical devices i.e. Medical Device
Directive – MDD

| | | | |
|---------------------------------|--|--|---------------------------------|
| Directives: | Council Directive 93/42/EEC concerning medical devices i.e., Medical Device Directive – MDD: Annex II – <i>Design Dossier Related</i> | | |
| Standards & Normative Documents | Harmonized Standards (published in the official Journal of the European Communities) applicable to the Product Group: | | |
| | EN/ISO 13485:2016 | EN/ISO10993-1:2018 | EN ISO 10993-7:2009 |
| | ISO 14971:2019 | EN ISO 11135-1:2014 | EN/ISO 11607-1:2019/Amd.1:2023. |
| | EN ISO 15223-1 | BS EN 1041:2008 | |
| Registrations & Certifications: | Certificate No. | Type | Issuance |
| | Intertek 0086774 | EN/ISO 13485:2016 Certificate | 31 January 2019 |
| | Intertek 41377747-01 | EC Design Examination Certificate | 26 February 2020 |
| | Intertek 41377748-01 | Full Quality Assurance System | 26 February 2020 |
| Notified Body: | Notified Body: | Notified Body No: | Certificate No: |
| | INTERTEK - SEMKO | 0413 | 41377747-01 41377748-01 |
| | Address: | Torshamnsgatan 73 Box 1103 164 22 Kista - Sweden | |
| ASC Responsible Authority | * <i>Amanda Lemus</i> | | Date: * 06/02/2025 |
| | – Management Representative | | |

Declaration of Conformity will be signed when issued.

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| AMERICOT | | |
|-----------------------|------------------------------|----------------------------------|
| Product Number | Size - Inches (w x l) | Size – Millimeter (w x l) |
| 20-01S | 1/4 x 1/4 | 6 x 6 |
| 20-04S | 1/2 x 1/2 | 13 x 13 |
| 20-05S | 1/2 x 1 | 13 x 25 |
| 20-06S | 1/2 x 1-1/2 | 13 x 38 |
| 20-07S | 1/2 x 3 | 13 x 76 |
| 20-08S | 3/4 x 3/4 | 19 x 19 |
| 20-09S | 1 x 1 | 25 x 25 |
| 20-10S | 1 x 3 | 25 x 76 |
| 20-11S | 1-1/2 x 1-1/2 | 38 x 38 |
| 20-12S | 3 x 3 | 76 x 76 |
| 20-13S | 3/4 x 3 | 19 x 76 |
| 20-14S | 3/8 x 3/4 | 10 x 19 |
| 20-15S | 5/8 x 3/4 | 16 x 19 |
| 20-17S | 3/8 x 1-9/16 | 10 x 40 |
| 20-19S | 1/8 x 1/8 | 3 x 3 |
| 20-22S | 3/8 x 3/8 | 10 x 10 |
| 20-25S | 3/8 x 1 | 10 x 25 |
| 20-26S | 3/8 x 2 | 10 x 51 |
| 20-27S | 3/4 x 2 | 19 x 51 |
| 20-28S | 1/4 x 3 | 6 x 76 |
| 20-30S | 1/4 x 1-1/2 | 6 x 38 |
| 20-32S | 1/2 x 2 | 13 x 51 |
| 21-01 | 1/4 x 6 | 6 x 152 |
| 21-02 | 1/2 x 6 | 13 x 152 |
| 21-03 | 3/4 x 6 | 19 x 152 |
| 21-04 | 1 x 6 | 25 x 152 |
| 21-05 | 1-1/2 x 6 | 38 x 152 |
| 21-06 | 2 x 6 | 51 x 152 |
| 21-07 | 3 x 6 | 76 x 152 |
| 21-08 | 3-1/2 x 6 | 89 x 152 |
| ULTRACOT | | |
| Product Number | Size - Inches (w x l) | Size – Millimeter (w x l) |
| 23-01 | 5/32 x 10/32 | 5 x 8 |
| 23-02 | 5/32 x 1/2 | 5 x 13 |
| 23-03 | 3/8 x 1/2 | 10 x 13 |
| 23-04 | 19/32 x 25/32 | 15 x 20 |
| 23-05 | 5/32 x 1-31/32 | 4 x 50 |
| 23-06 | 1/4 x 1-31/32 | 6 x 50 |
| 23-07 | 11/32 x 1-31/32 | 9 x 50 |
| 23-08 | 1/2 x 2-11/32 | 13 x 60 |
| 23-09 | 25/32 x 2-11/32 | 20 x 60 |
| 23-10 | 1-3/16 x 2-3/4 | 30 x 70 |
| 23-12 | 19/32 x 19/32 | 15 x 15 |

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| 23-15 | 1-3/16 x 3-17/32 | 30 x 90 |
|-----------------------|------------------------------|----------------------------------|
| 23-16 | 25/32 x 1-31/32 | 20 x 50 |
| 23-18 | 3/8 x 3-5/32 | 10 x 80 |
| 23-24 | 2-3/4 x 3-15/16 | 70 x 100 |
| RAY-COT | | |
| Product Number | Size - Inches (w x l) | Size – Millimeter (w x l) |
| 60-02 | 1/4 x 1/4 | 6 x 6 |
| 60-04 | 1/4 x 3 | 6 x 76 |
| 60-05 | 3/8 x 3 | 10 x 76 |
| 60-06 | 1/2 x 1/2 | 13 x 13 |
| 60-07 | 1/2 x 1 | 13 x 25 |
| 60-08 | 1/2 x 1-1/2 | 13 x 38 |
| 60-09 | 1/2 x 3 | 13 x 76 |
| 60-10 | 3/4 x 3/4 | 19 x 19 |
| 60-12 | 1 x 1 | 25 x 25 |
| 60-13 | 1 x 3 | 25 x 76 |
| 60-14 | 1-1/2 x 1-1/2 | 38 x 38 |
| 60-15 | 3 x 3 | 76 x 76 |
| 60-16 | 1/4 x 1-1/2 | 6 x 38 |
| 60-22 | 1-1/2 x 3 | 38 x 76 |
| 60-29 | 1/2 x 2 | 13 x 51 |
| 61-00 | 1/8 x 6 | 3 x 152 |
| 61-01 | 1/4 x 6 | 6 x 152 |
| 61-02 | 1/2 x 6 | 13 x 152 |
| 61-02S | 1/2 x 6 | 13 x 152 |
| 61-03 | 3/4 x 6 | 19 x 152 |
| 61-04 | 1 x 6 | 25 x 152 |
| 61-04S | 1 x 6 | 25 x 152 |
| 61-05 | 2 x 6 | 51 x 152 |
| 61-06 | 3 x 6 | 76 x 152 |
| 61-07 | 3-1/2 x 6 | 89 x 152 |
| 61-08 | 1-1/2 x 6 | 38 x 152 |
| UNIQCOT | | |
| Product Number | Size - Inches (w x l) | Size – Millimeter (w x l) |
| 67-02 | 1/4 x 1/4 | 6 x 6 |
| 67-04 | 1/4 x 3 | 6 x 76 |
| 67-05 | 3/8 x 3 | 10 x 76 |
| 67-06 | 1/2 x 1/2 | 13 x 13 |
| 67-07 | 1/2 x 1 | 13 x 25 |
| 67-08 | 1/2 x 1-1/2 | 13 x 38 |
| 67-09 | 1/2 x 3 | 13 x 76 |
| 67-10 | 3/4 x 3/4 | 19 x 19 |
| 67-12 | 1 x 1 | 25 x 25 |
| 67-13 | 1 x 3 | 25 x 76 |
| 67-14 | 1-1/2 x 1-1/2 | 38 x 38 |
| 67-15 | 3 x 3 | 76 x 76 |

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| 67-16 | 1/4 x 1-1/2 | 6 x 38 |
| 67-22 | 1-1/2 x 3 | 38 x 76 |
| 67-29 | 1/2 x 2 | 13 x 51 |
| 67-80 | 1/8 x 6 | 3 x 152 |
| 67-81 | 1/4 x 6 | 6 x 152 |
| 67-82 | 1/2 x 6 | 13 x 152 |
| 67-83 | 3/4 x 6 | 19 x 152 |
| 67-84 | 1 x 6 | 25 x 152 |
| 67-85 | 2 x 6 | 51 x 152 |
| 67-86 | 3 x 6 | 76 x 152 |
| 67-87 | 3-1/2 x 6 | 89 x 152 |
| 67-88 | 1-1/2 x 6 | 38 x 152 |
| DELICOT | | |
| Product Number | Size - Inches (w x l) | Size – Millimeter (w x l) |
| 63x00 | 0.08 x 0.80 | 2 x 20 |
| 63-01 | 5/32 x 10/32 | 5 x 8 |
| 63-02 | 5/32 x 1/2 | 5 x 13 |
| 63-03 | 3/8 x 1/2 | 10 x 13 |
| 63-04 | 19/32 x 25/32 | 15 x 20 |
| 63-05 | 5/32 x 1-31/32 | 4 x 50 |
| 63-06 | 1/4 x 1-31/32 | 6 x 50 |
| 63-07 | 11/32 x 1-31/32 | 9 x 50 |
| 63-08 | 1/2 x 2-11/32 | 13 x 60 |
| 63-09 | 25/32 x 2-11/32 | 20 x 60 |
| 63-10 | 1-3/16 x 2-3/4 | 30 x 70 |
| POLICOT | | |
| Product Number | Size - Inches (w x l) | Size – Millimeter (w x l) |
| 90-02 | 1/4 x 1/4 | 6 x 6 |
| 90-04 | 1/4 x 3 | 6 x 76 |
| 90-05 | 3/8 x 3 | 10 x 76 |
| 90-06 | 1/2 x 1/2 | 13 x 13 |
| 90-07 | 1/2 x 1 | 13 x 25 |
| 90-08 | 1/2 x 1-1/2 | 13 x 38 |
| 90-09 | 1/2 x 3 | 13 x 76 |
| 90-10 | 3/4 x 3/4 | 19 x 19 |
| 90-12 | 1 x 1 | 25 x 25 |
| 90-13 | 1 x 3 | 25 x 76 |
| 90-14 | 1-1/2 x 1-1/2 | 38 x 38 |
| 90-15 | 3 x 3 | 76 x 76 |
| 90-16 | 1/4 x 1-1/2 | 6 x 38 |
| 90-22 | 1-1/2 x 3 | 38 x 76 |
| 90-29 | 1/2 x 2 | 13 x 51 |
| 91-00 | 1/8 x 6 | 3 x 152 |
| 91-01 | 1/4 x 6 | 6 x 152 |
| 91-02 | 1/2 x 6 | 13 x 152 |
| 91-03 | 3/4 x 6 | 19 x 152 |
| 91-04 | 1 x 6 | 25 x 152 |

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| | | |
|-----------------------|------------------------------|----------------------------------|
| 91-05 | 2 x 6 | 51 x 152 |
| 91-06 | 3 x 6 | 76 x 152 |
| 91-07 | 3-1/2 x 6 | 89 x 152 |
| 91-08 | 1-1/2 x 6 | 38 x 152 |
| TELFA | | |
| Product Number | Size - Inches (w x l) | Size – Millimeter (w x l) |
| 80-04 | 1/4 x 3 | 6 x 76 |
| 80-05 | 3/8 x 3 | 10 x 76 |
| 80-06 | 1/2 x 1/2 | 13 x 13 |
| 80-08 | 1/2 x 1-1/2 | 13 x 38 |
| 80-09 | 1/2 x 3 | 13 x 76 |
| 80-11 | 3/4 x 3 | 19 x 76 |
| 80-12 | 1 x 1 | 25 x 25 |
| 80-13 | 1 x 3 | 25 x 76 |
| 80-14 | 3 x 3 | 76 x 76 |
| 81-06 | 1/2 x 6 | 13 x 152 |
| 81-11 | 3/4 x 6 | 19 x 152 |
| 81-13 | 1 x 6 | 25 x 152 |

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