

Declaration of Conformity

Manufacturer:



Thermo Fisher Scientific
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Authorized European Representative:



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Product:



| Catalog Number - Reference Number | Description |
|--------------------------------------|--|
| 5000-0012 | 1.2ml Sterile PP Cryogenic Vial |
| 5000-0020 | 2.0ml Sterile PP Cryogenic Vial |
| 5000-0050 | 5.0ml Sterile PP Cryogenic Vial |
| 5000-1012 | 1.0ml Sterile SYSTEM 100™ PP Cryogenic Vial |
| 5000-1020 | 2.0ml Sterile SYSTEM 100™ PP Cryogenic Vial |
| 5005-0015 | 15.0ml Sterile Specimen PP Cryogenic Vial |
| 5012-0012 | 1.2ml Sterile Bulk-packed PP Cryogenic Vial |
| 5012-0020 | 2.0ml Sterile Bulk-packed PP Cryogenic Vial |
| 5001-0012 | 1.2ml Sterile Bar-coded PP Cryogenic Vial |
| 5001-0020 | 2.0ml Sterile Bar-coded PP Cryogenic Vial |
| 5001-0050 | 5.0ml Sterile Bar-coded PP Cryogenic Vial |
| 5001-1020 | 2.0ml Sterile Bar-coded SYSTEM 100™ PP Cryogenic Vial |
| 300460-0012 | Fisher Brand Private-label Cryovial, 1.2ml |
| 300460-0020 | Fisher Brand Private-label Cryovial, 2.0ml |
| 300460-0050 | Fisher Brand Private-label Cryovial, 5.0ml |

Type of In Vitro Medical Device::

Cryogenic Vials

Standards Applied:

EN ISO 13485:2003 Medical devices — Quality management systems — Requirements for regulatory purposes

EN ISO 14971:2007 Medical devices — Application of risk management to medical devices

EN ISO 10993:2003 Biological evaluation of medical devices;
parts 1, 3, 5, 6, 11

EN ISO 11737-1:2006 Sterilization of medical devices — Microbiological methods

EN ISO 11137:2006 Sterilization of health care products — Radiation;
parts 1 and 2

EN ISO 11607:2006 Packaging for terminally sterilized medical devices;
parts 1 and 2

EN 980:2008 Symbols for use in the labeling of medical devices

EN 1041:2008 Information supplied by the manufacturer of medical devices

I herewith declare that the abovementioned products fulfill the Essential Requirements of EU Directive, 98/79/EC, as amended and the applied standards. The devices were assessed in conformance with the Essential Requirements, Annex I of the directive and the review of the technical documentation per Annex III of the directive.

All supporting documentation is retained under the premises of the manufacturer.

Signed: _____



date: _____



Tom Mousso
Regulatory Support Specialist
Thermo Fisher Scientific