

## Declaration of Conformity

### Manufacturer:



Thermo Fisher Scientific  
LSP - Rochester  
75 Panorama Creek Drive  
Rochester NY 14625-2385  
USA  
Phone: +1-585-586-8800

### Authorized European Representative:



Nunc A/S  
Thermo Fisher Scientific  
Kamstrupvej 90  
PO Box 280  
DK-4000 Roskilde  
Denmark  
Phone: +45 4631 2000

### Product:



| Catalog Number -<br>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<br>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