ThermoFisher
SCIENTIFIC

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:

REF

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: 9/14/2016

Tom Mousso
Regulatory Support Specialist
Thermo Fisher Scientific