ThermoFisher SCIENTIFIC

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Declaration of Conformity

This Declaration of Conformity, issued under our sole responsibility, is only valid when the instrument is used in accordance with the instructions for use.

Manufacturer's Name: Thermo Shandon Limited (Trading as Thermo Fisher Scientific)

Manufacturer's Address: Tudor Road, Manor Park, Runcorn, Cheshire, WA7 1TA, UNITED KINGDOM

Product Description: Automatic Stainer (Heated or Non-heated)

Product Name: **Thermo Scientific Gemini AS**
Product Common Name: **Gemini AS**
Instrument part numbers: *Heated: A81500101*
Unheated: A81500102
Saleable part numbers: *Heated: A81500001; A81500005*
Unheated: A81500002; A81500006
including accessories supplied as standard

Year of Marking (CE): 2012

This product conforms to the essential requirements of the following directives:

In Vitro Diagnostics Directive 98/79/EC

Machinery Directive 2006/42/EC

This product complies with the following International Standards:

EMC: EN 61326-2-6:2006
EN 61000-3-2:2006+A2:2009
EN 61000-3-3:2008
FCC CFR 47: Oct 2010 part 15.107 & 15.109 Class A

Safety: IEC 61010-1:2001 2nd Edition
IEC 61010-2-101 2nd Edition – both versions
IEC 61010-2-010 2nd Edition – heated version only
CAN/CSA C22.2 No. 61010-1 2nd Edition
UL Std No. 61010-1 2nd Edition

Issued by:

John W. Green
Director, Quality Assurance & Regulatory Affairs
Thermo Fisher Scientific
Anatomical Pathology Division

Issue 2

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Optional accessories considered subject to the In Vitro Diagnostic Medical Devices Directive (IVDD) are specifically identified on this Declaration of Conformity. Further supplies of standard accessories are treated as spares. Convenience aids offered as accessories are not subject to the IVDD.

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Thermo Shandon Limited
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