

DECLARATION OF CONFORMITY

Manufacturer: Fisher Diagnostics, a Division of Fisher Scientific Company, LLC,
a Part of ThermoFisher Scientific Inc.
8365 Valley Pike
Middletown, VA 22645-1905 USA

EU Authorized Representative: WMDE
Bergerweg 18
6085 AT Horn
The Netherlands

Conforming Product(s):

Product Code	Product Name/Description	EDMA Classification	GMDN Code(s)
A19611	Infinity™ Lithium (Li) Reagent for Beckman Coulter SYNCHRON Systems	11.03.01.06	55409
OSRT056	Infinity™ Lithium Reagent for Beckman Coulter AU® Chemistry Analyzers	11.03.01.06	55409
OSR61154	Infinity™ Ammonia Reagent for Beckman Coulter AU® Chemistry Analyzers	11.03.01.01	53208

(EC) Certificate: Self Certification - Non List A/B of Annex III

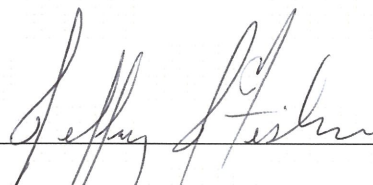
Directive: EU In Vitro Diagnostic Directive (IVDD) 98/79/EC

Notified Body: N/A

Original CE Mark: November 14, 2003

Quality System: Fisher Diagnostics quality system is certified to ISO 13485:2003 by BSI Group America, Inc., 12950 Worldgate Drive, Suite 800, Monument II, Herndon, VA 20170-6007 USA (No. FM620151).

We hereby declare under the sole responsibility of Fisher Diagnostic, that the product(s) aforementioned meet provisions of the In Vitro Diagnostic Directive (IVDD) 98/79/EC. All supporting documentation is retained on the premises of Fisher Diagnostics in Middletown, VA. A list of Harmonized Standards for which documented evidence of compliance is provided in the Technical File.



Jeffrey J. Fisher
Senior Director of Quality and Regulatory Affairs
Thermo Fisher Scientific, Middletown, VA USA

09 Dec 2016
Date