DECLARATION OF CONFORMITY

Manufacturer:	Fisher Diagnostics a division of Fisher Scientific Company, LLC a part of Thermo Fisher Scientific Inc. 8365 Valley Pike Middletown, VA 22645-1905 USA
European Representative: (Business Address)	MDCI Ltd. International Business Centre Spindle Way Crawley West Sussex RH10 1TG UK
(Registered Address)	MDCI Ltd. Arundel House 1 Liverpool Gardens Worthing West Sussex BN11 1SL UK
Product Name:	Beckman Reagents
Classification:	ANNEX III
Conformity Assessment Route:	Self-Certification

WE HEREBY DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC FOR IN VITRO DIAGNOSTIC MEDICAL DEVICES AND THE UK STATUTORY INSTRUMENT 2002 NO. 618, THE MEDICAL DEVICES REGULATIONS 2002 THAT APPLY. ALL SUPPORTING DOCUMENTATION IS RETAINED ON THE PREMISES OF THE MANUFACTURER.

EC Certificate:	N/A
Start of CE Marking:	March 17, 2008
Place, Date of Issue:	March 11, 2010 Middletown, VA
Signature:	Jeffrey L. Vaughan (name) Jeffrey L. Vaughan (title) Manager, QA Compliance and EHS

Section 1: General Information:

1a. Technical File Content

This Technical File (TF-0027) has been created to cover the Beckman family of clinical chemistry reagents manufactured by Fisher Diagnostics, a division of Fisher Scientific Company, LLC, a part of Thermo Fisher Scientific Inc. located at 8365 Valley Pike, Middletown, Virginia. These products are distributed in the United States (US) and in ex-US countries through distributors.

This Technical File includes the required information for the following products:

Fisher Diagnostics Part Number	Description
A46660	Gamma GT Reagent – IFCC Standardized for Beckman Coulter SYNCHRON and UniCel Systems
A19611	Infinity Lithium Reagent for SYNCHRON
A45288	Amylase EPS-G7 Reagent for Beckman Coulter SYNCHRON Systems

The above mentioned products are not listed in either List A or List B of Annex II of the In Vitro Diagnostic Medical Devices Directive (98/79/EC), nor are they products used for self-testing. These products are used by professionally trained staff in the medical or clinical laboratory. For these reasons, Fisher Diagnostics will follow Annex III of the 98/79/EC directive as the conformity assessment route.