



EC Declaration of Conformity

As legal Manufacturer, Axis-Shield Diagnostics Limited hereby declares that **3-Reagent Homocysteine Assay for SYNCHRON UniCel Kit** conforms to the applicable provisions of EC Directive 98/79/EC of the European Parliament.

Legal Manufacturer's Name: Axis-Shield Diagnostics Limited

Legal Manufacturer's Address Luna Place
The Technology Park
Dundee
DD2 1XA
United Kingdom

Manufacturing address: Luna Place
The Technology Park
Dundee
DD2 1XA
United Kingdom

Product(s) included in this declaration:

Product Name: **3-Reagent Homocysteine Assay for SYNCHRON UniCel**

Product Code: **FHYB100 (B08175)**

GMDN Code: **53751**

I, the undersigned, hereby declare that the *in vitro diagnostic* medical device(s) described above, conforms to the applicable provisions of EC Directive 98/79/EC concerning *in vitro* diagnostic medical devices.

This declaration is made in accordance with Annex III of the Directive.

Signature 

Name CLAIRE DORA

Position: Managing Director / RA Manager*

Date 2014-06-03

* Delete as appropriate