



### EC Declaration of Conformity

As legal Manufacturer, Axis-Shield Diagnostics Limited hereby declares that **Axis-Shield Liquid Stable (LS) 2-Part Homocysteine Reagent 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: **Axis-Shield Liquid Stable (LS) 2-Part Homocysteine Reagent Kit**

Product Code: **FHRK100**

**FHRWAU100 / 200 / 1000  
(FHRW110, FHRW130, FHRW210 and FHRW230)**

**FHRWR100 / 200 / 1000  
(FHRW110, FHRW130, FHRW210 and FHRW230)**

**FHRW100CN / 200CN / 1000CN**

**FHRWCN1 / 2 / 3**

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 Claire Dora

Name CLAIRE DORA

Position: Managing Director / RA Manager\*

Date 2014-04-09

\* Delete as appropriate