

Conformity Declaration

DiaSys Diagnostic Systems

GmbH · Alte Strasse 9 · 65558 Holzheim · Germany

declares in our own responsibility conformity of the product

InnovaStar®

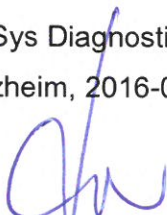
- Analyzer
- Accessories and spare parts

according to the essential requirements Annex I of the Directive 98/79/EC on in vitro diagnostic medical devices (IVD Directive).

The conformity was established by the manufacturer in a conformity assessment procedure according to Annex III (product grouping common/other IVD products) of the Directive 98/79/EC, except of Point 6.

Reagents, controls and consumables			
Product name	Product code	Product name	Product code
oneHbA1c IS	1 3329...	TruLab HbA1c liquid Level 1	5 9790...
Glucose/Hemoglobin IS	1 2491...	TruLab HbA1c liquid Level 2	5 9800...
CRP IS	2 7069...	System Solution InnovaStar	970 115
DiaCapil Sample Cups InnovaStar 10/500	970 113 and 970 114		

DiaSys Diagnostic Systems GmbH
 Holzheim, 2016-07-21



Peter Zöller
 Managing Director + CEO



“List of Applied Standards” is available on www.diasys-diagnostics.com