QUIDEL

EC Declaration of Conformity

Manufacturer: Quidel Corporation
10165 McKellar Court
San Diego, California 92121
USA

Product Names: **QuickVue® hCG Urine Test (Catalog #20109, #20109IN, #20109SC)**

Description: **The QuickVue® hCG Urine test is intended for the qualitative detection of human Chorionic Gonadotropin (hCG) in urine for the early detection of pregnancy.**

Classification: **General *In Vitro* Diagnostic Device**

Estimated Start of CE-Marking: **June 17, 2002**

Conformity Assessment Route: **Annex III of Council Directive 98/79/EC Concerning In vitro diagnostic devices**

Authorized Representative: **MDSS GmbH**
Schiffgraben 41
30175 Hannover, Germany

Quidel Corporation, being the manufacturer / distributor within the European Economic Area hereby declares that the product covered by the declaration conform to the Essential Requirements of EC Directive 98/79/EC. All supporting documentation is retained under the premises of the manufacturer.

This declaration is valid for all devices described in this document.

Signed: Jennifer S. Rial Date: 11/6/2018

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