

EU Declaration of Conformity



We hereby declare that the product described below conforms to all applicable requirements of Council Directive 98/79/EC for in vitro diagnostic medical devices.

Legal Manufacturer: Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY, 10591, USA

Place of Manufacture: Carclo Technical Plastics Inc.
6009 Enterprise Drive
Export, PA, 15632, USA

or

Carclo Technical Plastics Inc.
1141 West Grant Road
Tucson, AZ, 85705, USA

or

Carclo Technical Plastics Ltd.
47 Wates Way
Mitcham, Surrey, CR4 4HR, UK

or

CTP Taicang Co., Ltd
8 Xixin Road, Chengxiang Town
Taicang, Jiangsu Province
P.R. China 215411

EU Authorized Representative: Siemens Healthcare Diagnostics Manufacturing Ltd.
Chapel Lane
Swords, Co. Dublin, Ireland

Product Name: Cuvettes

Catalogue Number (REF): 10309546

Siemens Material Number (SMN): 10309546

Legacy Product Code: 078-K138-01
08044064

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Identifier: DoC_ADVIA Centaur Cuvettes

Version: 1.0

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This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Inc.

This declaration supersedes any declaration issued previously for the same product.

Signature:

Matthew Gee
Sr. Manager, Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
Tarrytown, NY, USA

2019-03-28

Date
[YYYY-MM-DD]

EU DECLARATION OF CONFORMITY