

EC 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.
500 GBC Drive, Mailstop 514, P.O. Box 6101
Newark, DE, 19714, USA

Place of Manufacture: Siemens Healthcare Diagnostics Inc.
500 GBC Drive, Mailstop 514, P.O. Box 6101
Newark, DE, 19714, USA

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

Product Name: Dimension® CHK Flex® reagent cartridge

Catalogue Number (REF): DF179

Siemens Material Number (SMN): 10481507

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Control Number: DoC_ DM_CHK_DF179

Version: 3.0

*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:

Victor Carrio
Sr. Manager Regulatory Affairs
Siemens Healthcare Diagnostics, Inc.
Newark, DE 19714

2019-02-10

Date
[YYYY-MM-DD]