Sysmex Europe GmbH · Bornbarch 1 · 22848 Norderstedt · Germany

Sysmex Europe GmbH
Bornbarch 1
22848 Norderstedt, Germany
Phone +49 40 52726-0
Fax +49 40 52726-100
info@sysmex-europe.com

February 14th, 2012/TKR

DECLARATION OF CONFORMITY

As a responsible representative of Sysmex Europe GmbH I hereby confirm that Sysmex clinical laboratory analysers and accessories as listed below currently are in conformity with

Directive 98/79/EC

of 27-October-1998

based upon test results using harmonised standards in accordance with Article 10 (1) of the Directive, and are labelled with a CE-mark according to this directive.

The standard used on electromagnetic compatibility is:

EN 61326-2-6:2006

Electrical equipment for measurement, control and laboratory use - EMC requirements -- Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment

Haematology Analysers:
XN-1000, XN-2000, XN-3000; XN-9000
XS-1000i, XS-800i, XS-500i
XT-4000i, XT-2000i, XT-1800i
XE-5000, XE-2100, XE-2100 L or D
pocH-100i
SE-9000, SE-9500, SF-3000
K-4500, KX-21N
F-820, F-520

Production Plant:
Sysmex Corporation Japan
314-2, Kitano,
Noguchi-cho, Kakogawa-shi,
Hyogo-ken 675
Japan

Coagulation Analysers:
CS-2100i, CS-2000i, CA-7000, CA-6000, CA-1500, CA-500 Series, CA-50

Urine Cell Analysers:
UF-1000i, UF-500i, UF-100i, UF-100, UF-50

Life Science Analysers:
RD-100i

System Products:
HST, CST, HST-N, CST-N, XE-AlphaN, SP-1000i, SP-10, LC-X

Sysmex Europe GmbH

i.A. Thomas Kröger
Director Regulatory Affairs + Legal Affairs