

E.C. DECLARATION OF CONFORMITY

This declaration of conformity is issued under the sole responsibility of the manufacturer:

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We declare that:

the Cleaning solution

Trade name: **Starrsed Disinfectant**

Product models:

Model name:	Product-ID (REF):
Starrsed Disinfectant	QRR 010947

GMDN code: 58236 (Buffered wash solution IVD, automated/semi-automated system)
Classification: General IVD

- Is in conformity with the requirements of the following EC directives:

98 / 79 / EC IVD devices (conformity assessment according Annex III of this directive)

- The following harmonized standards have been applied:
 - EN ISO 18113-2, In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
 - EN-ISO 15223-1, Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
 - EN ISO 14971, Medical devices - Application of risk management to medical devices
 - EN ISO 13485, Medical devices - Quality management systems - Requirements for regulatory purposes

The CE mark was applied for the first time on this IVD reagent in 2012.

Place: Zwaag, The Netherlands

Date: April 12, 2018

Signature:



Jan Buis

Stamp:



Function title: CEO
RR Mechatronics Manufacturing B.V.