

EU DECLARATION OF CONFORMITY

RR Mechatronics Manufacturing B.V.

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

P.O.Box 225

1620 AE HOORN

The Netherlands

RR Mechatronics Manufacturing B.V.

De Corantijn 13

1689 AN ZWAAG

The Netherlands

De Corantijn 13, 1689 AN Zwaag, The Netherlands

SRN: NL-MF-000023105

T +31 229 291 129

www.rrmechatronics.com

We declare that:

The Cleaning Solution:

Trade name/ Model: **Starrsed X-Clean**

Variant:	Product-ID (REF):	UDI-DI
Starrsed X-Clean	QRR010946	08719189137224

Basic UDI-DI (BUDI-DI): 8719189137H2C8FYCU

EMDN-code: W0103010105 Cbc-reagents (cleaning-/diluting-/lysing-/sheat-fluids)

Classification IVDR: Class A

Intended purpose: Product for the automatic cleaning of the Westergren pipettes in Starrsed ESR analyzers

is in conformity with the requirements of the following EU legislation(s):

Regulation (EU) 2017/746 In vitro diagnostic medical devices

(conformity assessment according Article 48, §10 of this regulation)

