TOSOH EUROPE N.V.

Declaration of Conformity

This is to certify that following In-Vitro Diagnostic Medical Devices:

Product name	Product code	Basic UDI-DI
Hemolysis Collection System 10 µL	0968780	5430000495000968780UC
Hemolysis Stability Solution 6 x 100 ml	0968700	5430000495000968700TL

are manufactured and sold by:

Tosoh Europe NV

Transportstraat 4, Tessenderlo, 3980, Belgium

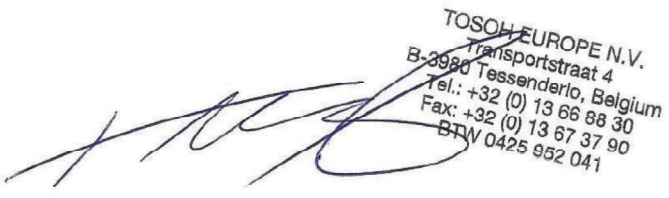
Single Registration Number: BE-MF-000000210

These products:

1. Are classified as Class A devices per Rule 5a of Annex VIII of the In-Vitro Diagnostic Medical Device Regulation 2017/746 as amended.
2. Are in conformity with the In Vitro Diagnostic Medical Device Regulation 2017/746 as amended.
3. Comply with the relevant general safety and performance requirements set out in Annex I of the In Vitro Diagnostic Medical Device Regulation 2017/746 as amended.
4. Are manufactured in facilities having a Full Quality System in place based on ISO 13485: 2016. This certificate has been issued by TÜV Rheinland.

This compliance has been documented using a checklist created from Annex I of the European In Vitro Diagnostic Medical Device Regulation, linked to all supporting Technical Documentation set out in Annexes II and III of this Regulation. This documentation includes both product specific and process (Quality System) specific documents.

- This Declaration is issued under the sole responsibility of Tosoh Europe NV.
- This Declaration is issued by Tosoh Europe NV and has unlimited time validity.
- This Declaration is signed below, certifying these requirements have been met and documented.



Ioannis Bekatoros

Senior Quality Assurance & Regulatory Affairs Manager

Thursday, May 19, 2022