

Manufacturer's Name: ELITechGroup Inc.

Manufacturer's Address: 370 West 1700 South
Logan, Utah 84321-8212, USA

European Authorized Representative: **MT Promedt Consulting, GmbH**
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This declaration is issued under the sole responsibility of the manufacturer, that the following products:

Item Number	Product Name	GMDN	EDMA
PRD-MSS-EL-08TKNE	Microsed-System® Automated ESR Analyzer	56691	23.09.01
PRD-X20-EL-08TKN	Mix-Rate® X20 Automated ESR Analyzer	56691	23.09.01

Type of Equipment: Automated Erythrocyte Sedimentation Rate Analyzer

IVDD Classification: Other/General...not list A or B or Self-Test

Conform to the requirements of RoHS 2 Directive, (2011/65/EU), the applicable section of the European Union Council Directive for In-Vitro Diagnostic Medical Devices, IVDD 98/79/EC, and the associated Essential Requirements under Annex I.

The following standards were applied:

- EN ISO 13485:2016
- EN ISO 14971:2012
- IEC 61010-1:2010/AMD1:2016
- IEC 61010-2-101:2015
- IEC 61326-1:2012
- IEC 61326-2-6:2012
- IEC 62471:2008
- EN ISO 15223-1:2016
- EN ISO 18113-1:2011
- EN ISO 18113-3:2011

And therefore, bears the CE Marking.

A technical file is maintained at ELITechGroup Inc. located at 370 West 1700 South, Logan, Utah, 84321, USA and a copy is provided to our European Authorized Representative.




Robert Ortiz
Regulatory Affairs Manager

2022-01-25
Date

Logan, Utah
Location