

CE Declaration of Conformity

Boule Medical AB declare that the products below

Type of product; Hematology reagents

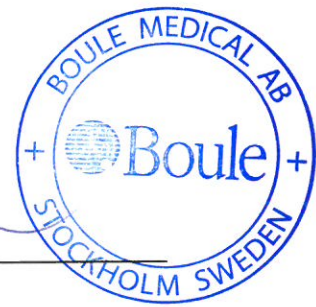
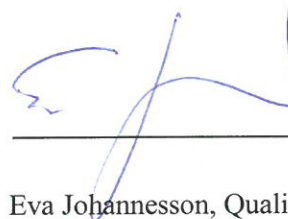
Article No	Brand name or trade mark
1504122	Medonic M-series Diluent, 20L
1504123	Medonic M-series Lyse 5L
1504128	Medonic M-series DualPack

are in conformity with the following regulations and directives and with harmonized standards:

Regulations/Directives	Standards
<i>98/79/EC In Vitro Diagnostic Medical Device Directive (IVD)</i>	Using Annex III as the conformity assessment procedure
<i>1907/2006/EC Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)</i>	
<i>1272/2008/EC classification, labelling and packaging of substances and mixtures (CLP)</i>	

Stockholm 2016-11-25

Date and place of issue



Eva Johannesson, Quality Assurance

