

EC Declaration of Conformity

Boule Medical AB declare that the products below

Type of product; Hematology reagents

Article No	Brand name or trade mark
1504082	Medonic CA 530/620 Diluent, 10 L
1503972	Medonic CA 530/620 Lyse, 10 L
1504332	Medonic CA 530/620 Diluent, 10 L, CN
1504333	Medonic CA 530/620 Lyse, 10 L, CN

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

Directives	Standards
98/79/EC <i>In Vitro Diagnostic Medical Device Directive (IVD)</i>	Using Annex III as the conformity assessment procedure

Stockholm 2014-08-28
Date and place of issue


Debora Thernström, Quality Assurance