

EC Declaration of Conformity

Boule Medical AB declare that the products below

Type of product; **Hematology calibrator/control**

Article No	Brand name or trademark
1504025	Boule Cal 1x3.0 ml
1504045	Boule Cal 2x3.0 ml
1504020	Boule Con-Diff L 1x4.5 ml
1504176	Boule Con-Diff L 6x4.5 ml
1504019	Boule Con-Diff N 1x4.5 ml
1504043	Boule Con-Diff N 6x4.5 ml
1504021	Boule Con-Diff H 1x4.5 ml
1504216	Boule Con-Diff H 6x4.5 ml
1504022	Boule Con-Diff Tri-L 6x4.5 ml
1504289	Boule Con-Diff L 25x3.0 ml
1504288	Boule Con-Diff N 25x3.0 ml
1504290	Boule Con-Diff H 25x3.0 ml

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

Stockholm 2022-06-02

Place and date of issue



Jesper Söderqvist, CEO