

## *EC Declaration of Conformity*

Boule Medical AB declare that the products below

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

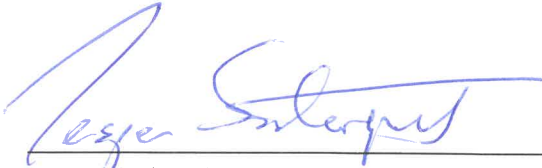
<b>Article No</b>	<b>Brand name or trademark</b>
1504375	Boule Cal-5Diff G2, 1x3mL
1504376	Boule Con-5Diff G2 Tri, 6x3mL
1504377	Boule Con-5Diff G2 High, 6x3mL
1504378	Boule Con-5Diff G2 Norm, 6x3mL
1504379	Boule Con-5Diff G2 Low, 6x3mL
1504380	Boule Con-5Diff G2 High, 1x3mL
1504381	Boule Con-5Diff G2 Norm, 1x3mL
1504382	Boule Con-5Diff G2 Low, 1x3mL

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

<b>Regulations/Directives</b>	<b>Standards</b>
<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

