

## *EC Declaration of Conformity*

Boule Medical AB declare that the products below

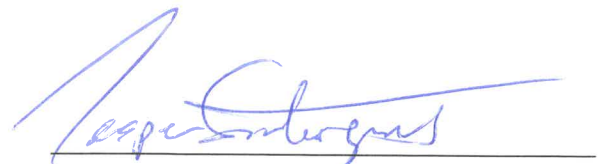
**Type of product; Hematology calibrator/control**

<b>Article No</b>	<b>Brand name or trademark</b>
1504517	Boule Cal-5Diff A1, 1x3mL
1504518	Boule Con-5Diff A1 Tri, 3x2x3mL
1504519	Boule Con-5Diff A1 Norm, 6x3mL
1504520	Boule Con-5Diff A1 Norm, 1x3mL
1504521	Boule Con-5Diff A1 Low, 1x3mL
1504522	Boule Con-5Diff A1 High, 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