

EC Declaration of Conformity

Boule Medical AB declare that the products below

Type of product; Cell counter

Medonic CellAnalyzer CA620

Serial number: _____

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

Directives	Standards
<i>98/79/EEC In Vitro Diagnostic Medical Device Directive (IVD)</i>	Using Annex III as the conformity assessment procedure
<i>2004/108/EEC Electro Magnetic Compatibility Directive (EMC) with amendment 92/31/EEC</i>	EN 61326-1:2006 EN 61326-2-6:2006
<i>2006/95/EEC Low Voltage Directive (LVD)</i>	IEC 61010-1: 1993

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Date and place of issue


Eva Johannesson

QA Manager

