Boule

EC Declaration of Conformity

Boule Medical AB declare that the products below

Type of product; ***Cellcounter***

Brand name or trade mark; ***Medonic CellAnalyzer CA620/530***

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

Directives	Standards
98/79/EC In Vitro Diagnostic Medical Device Directive (IVD)	Using Annex III as the conformity assessment procedure
89/336/EEC Electro Magnetic Compatibility Directive (EMC) with amendment 92/31/EEC	EN 61326:1997, with amendment EN 61326/A1 (1998)
73/23/EEC Low Voltage Directive (LVD)	EN 61010-1: 1993

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Date and place of issue

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