

CE Declaration of Conformity

Boule Medical AB declare that the product(s) below

Type of product; Cleaning solutions

Article No	Brand name or trade mark
1504112	Boule Enzymatic Cleaner, 100 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
<i>1907/2006/EC Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH),</i>	
<i>1272/2008/EC classification, labelling and packaging of substances and mixtures (CLP)</i>	

Stockholm 2016-11-25

Date and place of issue


Eva Johannesson, Quality Assurance

