


 Declaration of Conformity CE
 According to EU Directive 98/79/EC IVDD

Company	Sartorius Stedim Lab Ltd
Address	Sperryway
	Stonehouse Park
	Stonehouse
	Gloucestershire
	GL10 3UT
	<p>We herewith declare that the device described below fulfills the relevant fundamental safety requirements and health regulations specified by the appropriate EU-Directive, with respect to its design and construction and to the version as commercialized.</p> <p>This declaration becomes legally invalid if modifications are performed on the device which have not been certified by Sartorius Stedim Lab Ltd.</p>
Designation of Device	Vivaspin
Model, version	Vivaspin 4 Turbo 10K
Cat.-No.	VS04T01
	VS04T02
Relevant directives of the EU	EU Directive 98/79/EC IVDD
Applied harmonized standards	EN 13485:2012
The company has implemented a Quality management system according to	DIN EN ISO 9001:2008 EN 13485:2012



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Ralphina Pacini

Chris Biddell

4th April 2016