


EU Declaration of Conformity

(N° dc90147ben)

WE THE MANUFACTURER

Name	HORIBA ABX SAS
 Address	Parc Euromédecine Rue du Caducée BP 7290 34184 Montpellier Cedex 4 FRANCE
Single Registration Number	FR-MF-000000320

TAKE SOLE RESPONSIBILITY FOR AND HEREBY DECLARE THAT THE PRODUCT(S)

Device category	Clinical Chemistry Accessory
Product name	Sample Cup - Blue / Sample Cup - Green / Sample Cup - White / Sample Cup - Yellow
Models	A11A01765 / A11A01766 / A11A01767 / A11A01768
Basic UDI-DI	361023sample_cup7S
Country of origin	ITALY

Intended Use

The sample cups comprise *in vitro* diagnostics medical devices disposable cups, destined to be used on HORIBA Medical chemistry analyzers in order to contain samples of biological origin for the clinical chemistry analysis. Clinical laboratories use.

MEET(S) THE PROVISIONS OF THE FOLLOWING DIRECTIVES, REGULATIONS, STANDARDS AND COMMON SPECIFICATIONS

Regulations	Regulation (EU) 2017/746 on <i>in vitro</i> diagnostic medical devices Risk Class: A <input checked="" type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/>
IVDR conformity assessment route	<input checked="" type="checkbox"/> ANNEX II + ANNEX III + ANNEX IV (<i>Class A devices excluding sterile devices</i>)
Common Specifications	Not applicable

Montpellier, France
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Claire MALLIÉ
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