

## Compliance

Part CE 7smart

Part Number 08000

Year of Construction from 2011-03

This document certifies that the above mentioned apparatus was assembled and successfully tested at the SOTAX AG facility in Aesch, Switzerland.

- DQ = Design qualification
- Visual check of system
- Electrical safety check
- · Mechanical testing
- Calibration
- System testing
- Compatibility with the valid USP and Ph. Eur. Requirements

We confirm that all parts in contact with the dissolution media are made of inert material such as:

Cells	РММА
Metal parts	1.4435
General connection parts	PVDF / PVC
Tubing for medium without active agent	LDPE
Tubing for medium with active agent	PTFE
Waste tubes	PVC

Test data for this apparatus is available for inspection on request.

Aesch, 2019-08-06

Bruno Balli

**SOTAX Quality Management** 

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