



EC Declaration of Conformity

Sysmex Partec GmbH
Am Flugplatz 13
02828 Görlitz
GERMANY

Sysmex Partec GmbH declares via self-certification the compliance of the IVD, **Sheath Fluid**, specified in the annexed product list, classification general IVD, with the requirements of the Council Directive 98/79/EC, Annex I and III of 27th October 1998.

Any modification to the product or use of reagents, accessories or consumables, not authorized by the Sysmex Partec GmbH, will invalidate this declaration.

This declaration is based on the application of the Quality System approved for the design and development, production, service and final inspection of the products concerned in accordance with Annex IV of IVDD and the conformity of the full quality assurance system set out in Annex VII.

This declaration is supported by the Quality System certification based on the harmonized standard EN ISO 13485:2012 Quality System Certificate with reference number SX 60098060 0001 initially certified on date 3rd December 2014 and delivered by TÜV Rheinland®.

Görlitz, 2017-02-21

Sysmex Partec GmbH

A handwritten signature in blue ink, appearing to read "M. Guhl", written over a horizontal line.

Matthias Guhl
Chief Operating Officer (COO)

Sysmex Partec GmbH

A handwritten signature in blue ink, appearing to read "J. Spindler", written over a horizontal line.

Jens Spindler
Quality Management Representative (QMR)



Annex: Product List

Annex I to the Declaration of Conformity

Product List

Product Name	Article Number
Sheath Fluid	04-4007