

Declaration of Conformity

**Devyser AB
Instrumentvägen 19
SE-126 53 Hägersten, Sweden**

declare under our sole responsibility that the product

Devyser CFTR Core

Ref. No.: 8-A031

EDMA code: 16.01.01.01

UMDNS code: 24-335

to which this declaration relates is developed and manufactured in conformity with the requirements of Full Quality Assurance and that the product is in conformity with the Essential Requirements of the Directive 98/79/EC (LVFS 2001:7) and with the harmonized standards required by the directive 98/79/EEC article 9.1 annex III, other IVD products for professional use.

Hägersten, Sweden 2015-08-10



Ulf Klangby, CEO