

# Declaration of Conformity

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

**declare under our sole responsibility that the product**

## Devyser HFE v2

**Ref. No.: 8-A030.2**

EDMA code: 16.01.01.05

UMDNS code: 24-468

**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**

  
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**Ulf Klangby, CEO**