

DECLARATION OF CONFORMITY

Devyser AB
Instrumentvägen 19
SE-126 53 Hägersten
SWEDEN

Declare under our sole responsibility that the product

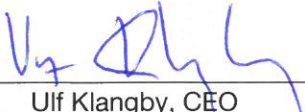
DEVYSER CFTR

Ref. No.: 8-A101

GTIN (8-test kit): 7350040631294
GTIN (24-test kit): 7350040631805
EDMA code: 16 01 01 01
GMDN code: 0
CIP code: 3189
UMDNS: 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 2016-09-26


Ulf Klangby, CEO