

DECLARATION OF CONFORMITY

Devyser AB
Instrumentvägen 19
SE-126 53 Hägersten
SWEDEN

Declare under our sole responsibility that the product

DEVYSER HBOC

Ref. No.: 8-A111

GTIN (24-test kit): 7350040631638

GTIN (48-test kit): 7350040631645

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 2020-06-29


Ulf Klangby, CEO