

DECLARATION OF CONFORMITY

Devyser AB
Instrumentvägen 19
SE-12653 Hägersten
SWEDEN

Single Registration Number (SRN): SE-MF-000001699

Declare under our sole responsibility that the product

Devyser Compact Ref. No.: 8-R017

Catalogue numbers	Number of tests
8-R017-25	25 tests
8-R017-50	50 tests
8-R017-100	100 tests

Basic UDI-DI: 7350040638A017MN

Risk class: C

Certificate: V12 090830 0005 Rev. 00

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 Annex I, General Safety and Performance Requirements, of regulation (EU) 2017/746 on in vitro diagnostic medical devices. Conformity assessment is based on a Quality Management System and on assessment of Technical Documentation, Annex IX Chapter I and III of regulation (EU) 2017/746, conducted by Notified Body TÜV SÜD Product Service GmbH Certification Body (0123). No CS has been used to demonstrate conformity.

Hägersten, Sweden 2023-02-28



Göran Rydin, COO