

## DECLARATION OF CONFORMITY

Devyser AB  
Instrumentvägen 19  
SE-126 53 Hägersten  
SWEDEN

Declare under our sole responsibility that the product


### DEVYSER BRCA

**Ref. No.: 8-A100**

GTIN (8-test kit): 7350040631263  
GTIN (24-test kit): 7350040631775  
EDMA code: 16 02 01 03  
GMDN code: 0  
CIP code: 3221  
UMDNS code BRCA 1: 24-319  
UMDNS code BRCA 2: 24-321

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 2017-02-24

  
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Ulf Klangby, CEO