SIEMENS

EU Declaration of Conformity

Digitally signed by Roman Constantin
Date: 2020.11.04 17:31:11 EET
Reason: MoldSign Signature
Location: Moldova

CE 0197

We hereby declare that the product described below conforms to all applicable requirements of Council Directive 98/79/EC for in vitro diagnostic medical devices.

Legal Manufacturer:	Siemens Healthcare Diagnostics Products Ltd. Glyn Rhonwy Llanberis, Gwynedd, LL55 4EL, UK
Place of Manufacture:	Siemens Healthcare Diagnostics Products Ltd. Glyn Rhonwy Llanberis, Gwynedd, LL55 4EL, UK
EU Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	IMMULITE® 2000 Anti-HBs
Catalogue Number (REF):	L2KAH2
Siemens Material Number (SMN):	10381318
Classification:	ANNEX II, List A
Conformity Assessment Route:	ANNEX IV
Notified Body:	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nuremberg, Germany Identification No. 0197
Document Identifier:	EC DEC_IMMULITE® 2000 Anti-HBs
Version:	03

This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products Ltd.
This declaration supersedes any declaration issued previously for the same product.

Signature: Robak Malgorzata

Digitally signed by Robak Malgorzata
DN: serialNumber=Z0020NKF, givenName=Malgorzata, sn=Robak, o=Siemens, cn=Robak Malgorzata
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2019-08-23

Malgorzata Robak
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Date [YYYY-MM-DD]

EU DECLARATION OF CONFORMITY