



EG-Konformitätserklärung/EC Declaration of Conformity

gemäß Anhang III der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998 *as per Annex III of Directive 98/79/EC of the European Parliament and Council of 27 October 1998*

Hersteller/Manufacturer: Hitachi High-Tech Corporation
1-17-1 Toranomon, Minato-ku
Tokyo 105-6409
Japan

Authorized Representative: Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim
Germany

Die Roche Diagnostics GmbH erklärt, dass das Produkt/die Produktfamilie
Roche Diagnostics GmbH declares that the product/the product line

Produktname/Product name: **cobas® pro integrated solutions**

Art.-Nr./Id. No.: **siehe Seite 2 / see page 2**

Beschreibung/Description: The **cobas® pro** integrated solutions is an in-vitro diagnostic device used for the quantitation of clinical chemistry / immunochemistry and Ion Selective Electrolyte parameters from various biological fluids.

auf das/die sich diese Erklärung bezieht, den Forderungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998 über In-vitro-Diagnostica (bzw. seine Umsetzung in nationales Recht der Mitgliedsstaaten in welchen das Produkt vermarktet werden soll) entspricht.
to which this declaration relates fulfils the requirements of Directive 98/79/EC of the European Parliament and Council of 27 October 1998 on in-vitro diagnostic medical devices (and its relevant transposition into the national laws of the Member States in which the device is intended to be placed on the market).

Mannheim, 10 March 2021

Roche Diagnostics GmbH

ppa./on behalf of the company

ppa./on behalf of the company

DocuSigned by:

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Ralf Zielenski
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Dr. Stefan Scheib
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Liste der **cobas**[®] **pro** integrated solutions Systemkomponenten: /
 List of **cobas**[®] **pro** integrated solutions system components:

Produktname / Product Name	Produkt Art. Nr. / Product Id. No.
cobas c 503 analytical unit	08463662001
cobas pro ISE analytical unit	08464537001
sample supply unit	08464502001
sample buffer	08463689001
SBL - TL - c 503	08463727001
SBL - DL - c 503	08463743001
cobas e 801 analytical unit	08454345001
SBL - DL - e 801	08462984001
Transport Belt 1	05642060001
Transport Belt 2	05642086001
Transport Belt 1 (w/o ISE)	05989990001
cobas 8000 B-Gate KIT	06372546001
cobas pro B-Gate update kit	08763640001
cobas pro liquid waste container	08763704001
cobas pro SSU	09205632001
cobas pro SB	09205675001
cobas pro SBL c 503	09205691001
cobas pro SBL e 801	09211888001
cobas pro transport line	09205683001
cobas pro Transport Belt (2 AU, 2 ISE)	09205713001
cobas pro Transport Belt (3 AU, 2 ISE)	09205721001
cobas pro Transport Belt (4 AU, 2 ISE)	09205730001
cobas pro B-Gate Upgrade Kit	09205756001