

EU Declaration of Conformity

We, Hamilton Bonaduz AG, Via Crusch 8, CH-7402 Bonaduz, Switzerland, confirm that this EU declaration of conformity is issued under the sole responsibility of Hamilton Bonaduz AG and that the product

Product name

AltoStar® Connect software

PN

911275

Basic UDI-DI

0763003269112758C

Installer Version

1.7.14

meets the following EC directives and regulations (including all applicable amendments):

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IVD Regulation

2017/746/EU Annex IV, self-declared

Class: A

Applied company quality management systems

EN ISO 9001:2015 EN ISO 13485:2016 Certification Body

TÜV Rheinland LGA Products GmbH

Tillystr. 2

90431 Nürnberg, Germany

Manufacturer

SRN: CH-MF-000013585

SWISSMEDIC Instrument Notification Nr.: CH-201910-0004

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EC REP (exclusive for Member States of the European Union)

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Authorize department for technical documents:

HAMILTON Quality Department Robotics

Hamilton Bonaduz AG

CFO

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Bonaduz, 2023.05.09