

EU-Declaration of Conformity according to Article 19 and Annex IV of Regulation (EU) 2017/745 (MDR)

Manufacturer

HCI Solutions AG
Untermattweg 8, 3027 Bern
Switzerland

SRN: CH-MF-000044367
CHRN: CHRN-MF-20001046

EU-Authorised Representative

MED-RAS GmbH Regulatory Affairs Service
Eichenallee 8H, 21521 Wohltorf
Germany

SRN: DE-AR-000006211

Product Identification

Product name: Documedis CDS.CE
Product type: Medical Device Software (Clinical Decision Support)
Risk class: Class IIa under MDR, Rule 11
Basic UDI-DI: 7649998068CDSRM
UDI-DI / GTIN: 7649998068024
Software version: 4.1.x.x
A detailed product description is provided in Annex I.

Declaration

HCI Solutions AG hereby declares under its sole responsibility that the above-mentioned product complies with the applicable requirements of Regulation (EU) 2017/745 on medical devices (MDR) and the Swiss Medical Devices Ordinance (MepV; SR 812.213).

The conformity assessment procedure applied: MDR Annex IX – Conformity assessment based on a quality management system and technical documentation.

Notified body

DQS Medizinprodukte GmbH
August-Schanz-Straße 21, 60433 Frankfurt am Main
Germany

Body Number: 0297
Certificate registration no.: 31623185 MDR2017Q
Certificate ID: 1000226650

Harmonized standards applied:

- EN ISO 13485:2016 + AC:2018 + A11:2021
- EN ISO 14971:2019 + A11:2021
- EN ISO 15223-1:2021

In addition, the following state-of-the-art technical specifications were applied:

- EN 62304:2006+A1:2015
- IEC 81001-5-1:2021

Location, date (DD-MM-YYYY):

Bern, 19-12-2025

Person
Function
Company

Markus Sager
Chief Executive Officer
HCI Solutions AG

Person
Function
Company

Eric Rochat
Person Responsible for Regulatory Compliance (PRRC)
HCI Solutions AG

Appendix I

Product name	MDx Code	MDx Term Name	Intended purpose
Documedis CDS.CE	MDA 0315	Software	<p>The product Documedis CDS.CE is a web-based software that checks the used or planned medication of a patient for health risks. In this way, the software supports healthcare professionals from doctors' practices, hospitals, pharmacies, spitex and homes in making decisions about medication therapy. The support is provided with the help of various checks that give medication warnings and recommendations.</p> <p>The product is offered as a web API and web application and can be integrated by primary system providers from the healthcare sector into their software.</p>