



Name of Manufacturer SWITCH IT GMBH

Max-Emanuel-Straße 2

94036 Passau Germany

Single Registration Number (SRN) **DE-MF-000040960** 

We hereby declare under our sole responsibility that the product:

Product Name [switch it] Ready Reader / see annex

Basic UDI-DI 4052813RR-PLA-H-MIN-9F

Nomenclature EMDN Q0210030202 (ECRI) 11-667, GMDN Code 32816

Risk Class Class I – non-sterile, no measuring function

Conformity Assessment Procedure in accordance with Article 52 (7) for medical devices

complies with the provisions of the following legal regulation:

Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices

Complies with European standard EN 14139

and complies with the provisions of the following legislation:

Complies with European standard EN ISO 12312-1

and complies with the provisions of the following legislation:

Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH)

We maintain a systematic procedure for post-market surveillance of the product.

Passau, 10.06.2024

Place and Date of Issue

Bernd Maute Managing Director

Bernd Moute

Bernd Maute,

Person Responsible for Regulatory

Bornd Moule

Compliance (PRRC)



## Annex

Model	
SIF-D07A-1.0 53/18	
SIF-D07A-1.5 53/18	
SIF-D07A-2.0 53/18	
SIF-D07A-2.5 53/18	
SIF-H07A-1.0 55/18	
SIF-H07A-1.5 55/18	
SIF-H07A-2.0 55/18	
SIF-H07A-2.5 55/18	