



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] Frames / Models – see annex**

Basic UDI-DI **42557991F-PLA-V-ADL-GF**
42557991F-PLA-H-ADL-AR
42557991F-PLA-RL-ADL-CK

Nomenclature **EMDN Q02100299 (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**

is in conformity with the provisions of the following legal acts:

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

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

The product complies with the European Standard EN ISO 12870.

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

Passau, 06.08.2025

Place and Date of Issue

Bernd Maute
Managing Director

Bernd Maute,
Person Responsible for Regulatory
Compliance (PRRC)



Annex

Model as Frame	Model as Interchangeable Rim
	"switch it" kit SI-G1034
	"switch it" kit SI-G1035
	"switch it" kit SI-G2021A
	"switch it" kit SI-G2079A
	"switch it" kit SI-G2097B
	"switch it" kit SI-G2116A
	"switch it" kit SI-G2268A
	"switch it" kit SI-G2350A
"switch it" Mod. SI-2569 54/16	"switch it" kit SI-G2569
"switch it" Mod. SI-2570 55/18	"switch it" kit SI-G2570
"switch it" Mod. SI-2571 54/15	"switch it" kit SI-G2571
"switch it" Mod. SI-2572 55/18	"switch it" kit SI-G2572
"switch it" Mod. SI-2573 52/18	"switch it" kit SI-G2573
"switch it" Mod. SI-2574 52/18	"switch it" kit SI-G2574
"switch it" Mod. SI-2575 53/17	"switch it" kit SI-G2575
"switch it" Mod. SI-2576 50/18	"switch it" kit SI-G2576
"switch it" Mod. SI-2577 55/18	"switch it" kit SI-G2577
"switch it" Mod. SI-2578 54/18	"switch it" kit SI-G2578
"switch it" Mod. SI-2579 55/18	"switch it" kit SI-G2579
"switch it" Mod. SI-2580 54/18	"switch it" kit SI-G2580
"switch it" Mod. SI-2581 52/17	"switch it" kit SI-G2581
"switch it" Mod. SI-2582 54/18	"switch it" kit SI-G2582
"switch it" Mod. SI-2583 54/18	"switch it" kit SI-G2583
	"switch it" kit SI-GPSI-CHAKRA2-A