



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-OT-V-ADL-TR**
42557991F-OT-H-ADL-N3
42557991F-OT-RL-ADL-R3

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" Mod. SI-6030 53/18 | "switch it" kit SI-G6030 |
| "switch it" Mod. SI-6031 58/18 | "switch it" kit SI-G6031 |
| "switch it" Mod. SI-6032 54/18 | "switch it" kit SI-G6032 |
| "switch it" Mod. SI-6033 53/18 | "switch it" kit SI-G6033 |
| "switch it" Mod. SI-6034 53/18 | "switch it" kit SI-G6034 |
| "switch it" Mod. SI-6035 54/18 | "switch it" kit SI-G6035 |
| "switch it" Mod. SI-9242 53/18 | "switch it" kit SI-G9242 |
| "switch it" Mod. SI-9243 51/18 | "switch it" kit SI-G9243 |
| "switch it" Mod. SI-9256 55/18 | "switch it" kit SI-G9256 |
| "switch it" Mod. SI-9257 55/18 | "switch it" kit SI-G9257 |
| "switch it" Mod. SI-9258 55/18 | "switch it" kit SI-G9258 |
| | "switch it" kit SI-GPSI1-A |
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