Declaration of Conformity

We
DocCheck Shop GmbH
SRN: DE-MF-000009070
Vogelsanger Street 66
50823 Cologne
Germany

herby declare under our sole responsibility that the CE marked product, to which this declaration relates

Dermatoscope "Scaut"
Art.-No. 103842.0
Basis UDI-DI: 42509258103842MW

The object of the declaration described above is in conformity with the following Union legislation:

- Regulation (EU) 2017/745 on medical devices (MDR)
- Directive 2014/53/EU on radio equipment (RED)

The product is classified, according to the rules of Annex VIII, rule 10 of the Medical Device Regulation 2017/745, as a **Class I device**

and

meets all applicable basic safety and performance requirements, according to Annex I of the Medical Device Regulation 2017/745.

The device meets all essential requirements under Article 3 of the Radio Equipment Directive 2014/53/EU.

Conformity is declared in accordance with the following harmonized standards and specifications:

MDR

EN 13485, EN 14791, EN 20417, EN 60601-1, EN 62366-1, EN 15223-1, EN 60601-1-2, EN 10993-1, EN 62304

RED

ETSI EN 301 489-1 V2.2.3, ETSI EN 301 489-17 V3.2.4, EN 62311:2019, ETSI EN 300 328 V2.2.2

The provisions of the Regulation (EU) 2017/745 (MDR), Annex IV on medical devices and of the Directive 2014/53/EU, Annex VI on radio equipment are fulfilled.

Authorised Representative CH-Rep for medical devices:
TAS SAT AG,
Chamerstrasse 172 CH-6300 Zug

This Declaration of Conformity remains valid until it is superseded by a revised version due to product modifications.

Köln, den 01.08.2025

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