

EC Declaration of Conformity

Manufacturer: Soteria Biotech Co., Ltd.
12F, No. 365, Fude 3rd Rd.,
Xizhi Dist., New Taipei City 22151
Taiwan
SRN: TW-MF-000013120

European Authorised Representative: MT Promedt Consulting GmbH
Ernst-Heckel-Straße 7
66386 St. Ingbert,
Germany
SRN: DE-AR-000000085

Product Name: Soteria One Point Zero (version: 1.0)

Internal software version: Soteria one point zero-20170721143733

Basic UDI-DI: 471988033001FV

GMDN Code: 41670 Radiological picture archiving and communication system (PACS) software

UMDNS Code: 16247 Picture archiving and communication systems (PACS), Radiology

Intended purpose: Soteria One Point Zero is a cloud based standalone software platform designed to display and analyze head and neck medical images

Classification: Class IIa, Rule 11 per Annex VIII of Regulation 2017/745

Conformity Assessment Route: Annex IX Chapter I and III of Regulation 2017/745

We herewith declare that the above mentioned product meet the provisions of Medical Device Regulation 2017/745. All supporting documentation is retained under the premises of the manufacturer.

Common Specifications Used: N/A

Notified Body: TÜV SÜD Product Service GmbH
Zertifizierstellen, Ridlerstraße 65, 80339 MÜNCHEN
Germany

NB Identification number: CE0123

Certificate No.: G1 102623 0002 Rev. 00

Issue Date: 2020-01-07

Expiry Date: 2024-05-26

The aforementioned declaration of conformity is exclusively under the responsibility of the CEO of Soteria Biotech Co., Ltd.

New Taipei City 2021.9.15
Place, Date

Hung-Ta Hsiao
Hung-Ta Hsiao, CEO