



Assurance Continuity Maintenance Report

BSI-DSZ-CC-0519-V5-2024-MA-01

**Stationäres eHealth Kartenterminal ORGA 6141
online, V3.9.1:2.0.0/1.2.0**

from

Worldline Healthcare GmbH



SOGIS
Recognition Agreement
for components up to
EAL 4

The IT product identified in this report was assessed according to the procedures on Assurance Continuity [1] and the developer's Impact Analysis Report (IAR). The baseline for this assessment was the Certification Report, the Security Target and the Evaluation Technical Report of the product certified by the Federal Office for Information Security (BSI) under BSI-DSZ-CC-0519-V5-2024.



The change to the certified product is at the level of implementation and an update of the user guidance. The identification of the maintained product is indicated by a new version number compared to the certified product. The changes lead to an update of the user guidance.

Considering the nature of the change leads to the conclusion that it is classified as a minor change and that certificate maintenance is the correct path to continuity of assurance.



Common Criteria
Recognition Arrangement
recognition for components
up to EAL 2 and ALC_FLR
only

The resistance to attacks has not been re-assessed in the course of this maintenance process. Therefore, the assurance statement as outlined in the Certification Report BSI-DSZ-CC-0519-V5-2024 dated 24 September 2024 is of relevance and has to be considered when using the product. Details can be found on the following pages.

This report is an addendum to the Certification Report BSI-DSZ-CC-0519-V5-2024.



Bonn, 21 May 2025

The Federal Office for Information Security

Assessment

The IT product identified in this report was assessed according to the procedures on Assurance Continuity [1] and the Impact Analysis Report (IAR) [2]. The baseline for this assessment was the Certification Report of the certified product (Target of Evaluation, TOE) [3], its Security Target and the Evaluation Technical Report as outlined in [3].

The vendor for the Stationäres eHealth Kartenterminal ORGA 6141 online, V3.9.1:2.0.0/1.2.0, Worldline Healthcare GmbH, submitted an IAR [2] to the BSI for approval. The IAR is intended to satisfy the requirements according to the procedures on Assurance Continuity [1]. In accordance with those requirements, the IAR describes (i) the changes made to the certified TOE, (ii) the evidence updated as a result of the changes and (iii) the security impact of the changes.

The Stationäres eHealth Kartenterminal ORGA 6141 online, V3.9.1:2.0.0/1.2.0 was changed due to some error corrections and optimizations, non-security relevant adaptations and an update of open source components. Configuration Management procedures required a change in the product identifier. Therefore the version number changed from V3.9.0 to V3.9.1.

A non-TOE Wireguard VPN client and a Web-App/RMI-Admin (remote based) enabling of pairing with the eHKT was added. The changes further lead to an update of the user guidance [6]. The Security Target [4] was editorially updated.

Conclusion

The maintained change is at the level of implementation and guidance documentation. The change has no effect on product assurance, but the updated guidance documentation has to be followed.

Considering the nature of the change leads to the conclusion that it is classified as a minor change and that certificate maintenance is the correct path to continuity of assurance.

The resistance to attacks has not been re-assessed in the course of this maintenance process. Therefore, the assurance statement as outlined in the Certification Report BSI-DSZ-CC-0519-V5-2024 dated 24 September 2024 is of relevance and has to be considered when using the product.

Obligations and notes for the usage of the product:

All aspects of assumptions, threats and policies as outlined in the Security Target not covered by the TOE itself need to be fulfilled by the operational environment of the TOE.

The customer or user of the product shall consider the results of the certification within his system risk management process. In order for the evolution of attack methods and techniques to be covered, he should define the period of time until a re-assessment for the TOE is required and thus requested from the sponsor of the certificate.

Additional Note: The strength of the cryptographic algorithms was not rated in the course of the product certification and this maintenance procedure (see BSIG¹ Section 9, Para. 4, Clause 2).

For details on results of the evaluation of cryptographic aspects refer to the Certification Report [3] chapter 9.2.

This report is an addendum to the Certification Report [3].

1 Act on the Federal Office for Information Security (BSI-Gesetz - BSIG) of 14 August 2009, Bundesgesetzblatt I p. 2821

References

- [1] Common Criteria document “Assurance Continuity: CCRA Requirements”, version 3.1, 29 February 2024
Common Criteria document “Assurance Continuity: SOG-IS Requirements”, version 1.2, March 2024
- [2] ORGA 6141 online / Neo V3.9.0:1.2.0 / 2.0.0 Auswirkungsanalyse IAR, V1.0, 19.03.2025, Worldline Healthcare GmbH (confidential document)
- [3] Certification Report BSI-DSZ-CC-0519-V5-2024 for Stationäres eHealth Kartenterminal ORGA 6141 online 3.9.0:2.0.0/ 3.9.0:1.2.0, 24.09.2024, Bundesamt für Sicherheit in der Informationstechnik
- [4] Security Target for the Evaluation of the Product ORGA 6141 online, V 4.1.23, 17.02.2025, Worldline Healthcare GmbH
- [5] ConfigList Document References, Version 1.22.0, 13.05.2025, Worldline Healthcare GmbH (confidential document)
- [6] Bedienungsanleitung Stationäres eHealth-Kartenterminal ORGA 6141 online Hardware-Version 1.2.0 und 2.0.0 (ORGA Neo) mit Firmware-Version 3.9.1, Version 25.4.2, 5.4.2025, Worldline Healthcare GmbH
- [7] ADV Document References, Version 1.022, 13.05.2025, Worldline Healthcare GmbH (confidential document)