

 Ahlstrom Germany GmbH	TFN documentation S6_FB_0001_ EU_Declaration_of_Conformity	Revision: 02 Stand: 28.04.2023 Seite 1 von 1
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Manufacturer: Ahlstrom Germany GmbH
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SRN: Registration is currently in preparation.

Basic – UDI – DI: 42555909SCC-01-8.460.ACN

Product name: TFN-Specimen Collection Card

Item group: 8.460.xxxx.A

Intended purpose: Specimen collection paper for absorption, storage and transport of human whole blood samples.

Classification: Risk class A

Declaration: We declare as manufacturer with sole responsibility that the TFN-Specimen collection card paper mentioned above, produced by us, fulfills all essential requirements of Directive (EU) 2017/746.

Harmonised standard: EN ISO 13485:2016/A11:2021
EN ISO 15223-1:2021
EN ISO 14971:2019/A11:2021
EN 13612:2002/AC:2002
EN ISO 18113-1:2011

Product standard: NBS01-Ed7:2021

Place, date: Bärenstein, 01.05.2023
Name, function: Hartmut Ott, Plant & Operational Product Manager

Signature: 

Validity: This declaration is valid until 30.04.2024.
In the case of unauthorized modifications in the product or a not intended use, this declaration becomes invalid.