

 AHLSTROM MUNKSJÖ Ahlstrom - Munksjö Germany GmbH	TFN documentation S6_FB_0001_EU_declaration_of_conformity	Revision: 01 Stand: 23.05.2022 Seite 1 von 1
---	---	--

Manufacturer: Ahlstrom - Munksjö Germany GmbH
Niederschlag 1
09471 Bärenstein
Deutschland
T: +49 (0) 37347 83 - 0
F: +49 (0) 37347 83 - 64

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 13612:2002
EN ISO 14971:2012
EN ISO 18113-1:2011

Product standard: NBS01-A6:2013 Blood Collection on Filter Paper for Newborn Screening Programs

Place, date: Bärenstein, 25.05.2022
Name, function: Hartmut Ott, Plant & Operational Product Manager

Signature: 

Validity: This declaration is valid until 24.05.2023.
In the case of unauthorized modifications in the product or a not intended use, this declaration becomes invalid.