AHLSTROM MUNKSJÖ	**EU Declaration of Conformity** **accordingly Directive 98/79/EG, Annex III**	Revision: 14/01.02.2017 Dok.-Nr.: 30705/ EN-UA
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Manufacturer:

Ahlstrom Germany GmbH
Niederschlag 1
09471 Bärenstein
Deutschland

T: +49 (0) 37347 83 - 0
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Product name: TFN-Specimen Collection Card

Item group: 2.460.00054

Indented use: Specimen collection paper for absorption, storage and transport of human sample blood (dry blood spot sample) for In-Vitro-diagnostics of Newborn screenings and HIV1 analysis.

Classification:
General IVD
EDMS 26-02 (sample processor)

Declaration: Within the meaning of Annex III of Directive 98/79/EC we declare as manufacturer with sole responsibility that the specimen collection paper mentioned above fulfills all essential requirements of Directive 98/79/EC of the European Parliament and the Council of 27.10.1998 on In vitro diagnostics.

Harmonised standard:
DIN EN ISO 13485:2012-11
DIN EN 980:2008-08
DIN EN 13612:2002-08
DIN EN ISO 14971:2013-04
DIN EN ISO 18113-1:2013-01

Product standard: The requirements of the product standard CLSI document NBS01-A6 - Blood Collection on Filter Paper for Newborn Screening Programs are fulfilled.

Validity: This document is valid until 31.01.2018.

Date| Signature	11.05.2017	11.05.2017
Name | Function	Thomas Foltyn Plant Manager	Maria-Isabel Buhler Quality Manager

In the case of unauthorized modifications in the product or a not indented use this declaration becomes invalid.

Digitally signed by Iurcu Nicolae
Date: 2019.12.05 21:33:20 EET
Reason: MoldSign Signature
Location: Moldova