

Product declaration

Ahlstrom-Munksjö TFN:

- is within the meaning of the European Directive 98/79/EC, IVD Device.
- is manufactured according to Quality Management System DIN EN ISO 13485 for Medical devices.
- Ahlstrom-Munksjö TFN 100% pure cotton fibers and contains no wet strength additives.
- every batch is tested by an independent accredited laboratory for release.
- meets the requirements of Clinical Standards Laboratory Institute (CLSI) Approved Standard: **NBS01-A6 „Blood Collection on Filter Paper for Newborn Screening Programs-Sixth Edition“**:

Physical properties	Units	Method	Requirements	Typical Value
Basis Weight	g/m ²	DIN EN ISO 536	179 g/m ² ± 5%	179
Ash Content (800°C)	%	DIN 54370	≤ 0.1 %	0.04
pH-value		DIN 53124	5.7 to 7.5	7.0
Blood spot diameter	mm	NBS01-A6	16 ± 1 mm	16
Blood absorption time	s/ 100 µl	NBS01-A6	5 – 30 s	12
Blood serum absorption volume	µl	NBS01-A6	1.54 ± 0.17µl	1.54



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