

Textilní zkušební ústav, s.p.

TEXTILNÍ ZKUŠEBNÍ ÚSTAV, s.p.

(TEXTILE TESTING INSTITUTE)
CERTIFICATION BODY FOR THE CERTIFICATION OF PRODUCTS
CEJL 480/12, ZÁBRDOVICE, 602 00 BRNO, CZECH REPUBLIC

issues

Client:

LP MAN s.r.o., K Zornici 1654/18, 957 01 Bánovce nad Bebravou, Slovakia

TESTIMONIAL

No.: 20 - 140

Product:

Overall MEDIMAN 2020

Material composition: 100 % polypropylene – 2 layers nonwoven textile ("melt blown") /100 % polypropylene – inner nonwoven textile ("spun bond"); with antibacterial component - silver (1,2 weight %)

Product meets selected parameters of technical specification:

- EN 14126:2003 Protective clothing Performance requirements and tests methods for protective clothing against infective agents with respect to wet and dry microbial penetration product meets class 3 after 15 cycles of washing at 50 °C)
- EN 13795-1:2019 Surgical clothing and drapes Requirements and test methods Part 1: Surgical drapes and gowns with respect to wet and dry microbial penetration tested after 15 cycles of washing at 50 °C product meets requirements for less critical product area (standard and high performance) and requirements for critical product area (standard performance). The product does not change dimensions due to sterilization.
- ASTM E 2149-13a Standard Test Method for Determining the Antimicrobial Activity of Antimicrobial Agents Under Dynamic Contact Conditions product presents high reduction of bacteria after 10 cycles of washing at 50 °C

Table: Assessment of test results

Parameter	Test method	Measur. unit	Value required	Value identified	Assessment
Dimension changes after 10x sterilization (MD/CD)	EN ISO 5077	%	≤ 3	- 2,5 / - 2,0	PASS
Reduction of bacteria R - after 10x washing at 50 °C	ASTM E 2149-13a	%		92,9 / 99,9 ¹⁾ (after 8/ 24 h.)	High reduction
Microbial penetration - dry (log CFU) - wet (I _B /penetration time t) - after 15x washing at 50 °C	EN 14126 (EN ISO 22612) (EN ISO 22610)	log CFU min.	class 3 ≤1 30 <t≤45< td=""><td>0,78 3,7</td><td>PASS class 3 class 3</td></t≤45<>	0,78 3,7	PASS class 3 class 3
Microbial penetration - dry (CFU - Uq) - wet (IB) - after 15x washing at 50 °C	EN 13795-1 (EN ISO 22612) (EN ISO 22610)	CFU IB	≤ 300 ≥ 2,8	2,0 3,7	PASS PASS *

Legend: *- it meets requirements of EN 13795-1 for standard performance of product (critical and less critical product area) and for high performance of product (less critical product area)

The Testimonial has been issued on the basis of the application No. COV/20/375 from 25.10.2020. The base for the Testimonial is Test Report No. AZL 20/1004-01 (16.09.2020), AZL 20/1004-02 (20.10.2020), AZL 20/0934 (24.08.2020), issued by the accredited test laboratory of TZÚ Brno. Detailed test results and conditions of testing are described in these test reports.

Testimonial issued: Brno, 26.10,2020

Validity up to: 31.10.2022

TZU KROW CERTIFIKACI VÝROSO * BRNO * CHAULEUN *

Ing. Svatava Horáčková Head of the Certification Body

Issued by: