	Technical Data Sheet
Use in	• Pharmaceutical industry in clean rooms and isolators • For industrial, laboratory & research applications only • Basic medium in the ampoule according to EP 2.6.1 and USP <71>
Use for	• Qualitative surface test by swabbing • All-in-one swab for sampling in critical environments • Environmental monitoring of dry surfaces, filling needles, tubing and surfaces that are hardly accessible with contact plates in cleanrooms, RABS and isolators • Detection of micro-organisms by swab sampling and incubation • Neutralization of residues of disinfectants
Typical composition per litre	• <u>Growth medium in ampoule</u>: Casein peptone 17 g; NaCl 5 g Glucose-D(+) x H_2O 2.5 g; Polysorbate 80 5 g K_2HPO_4 2.5 g; Neutralizer PLUS* Soy peptone 3 g * Optimized for neutralization of residues of disinfectants • <u>Pre-moistening solution</u>: NaCl 9 g This medium can be adjusted and / or supplemented according to the performance criteria required.
Irradiation	• Gamma-sterilized with > 25 kGy (25 - 45 kGy)
Filling volume	• Growth medium in ampoule: 2 mL • Pre-moistening solution: 400 µL
Packaging	• Triple bagged, packs of 6 swabs • Transparent • High barrier foil for H_2O_2 as well as for water-vapour • 20 packs of 6 swabs per packaging unit • Size: ○ Innermost foil – 280 x 80 mm (contains 1 PMM-Swab) ○ Middle foil – 340 x 210 mm (contains 6 PMM-Swabs) ○ Outer foil – 400 x 240 mm (contains 6 PMM-Swabs) ○ Cardboard box – 380 x 190 x 380 mm (contains 120 PMM-Swabs)
Swabs per box	• 120 swabs
Shelf life	• 8 months from production date (ext. to 12 months under investigation)

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Storage	• Recommended storage temperature: 2 - 25 °C • Should be stored at temperatures as stable as possible • Should be stored upright
Label	• On the lower unit of the device
Label information	• Product name: PMM Swab • Expiry date: YYYYMMMDD ➔ MMM in letters (e.g.: 2023Nov04) • Lot-number • Individual number • Barcode
Barcode	• 2-dimensional (data matrix), 20 digits: • Digits 1-3: Art.-No. • Digits 4-9: Lot-Number • Digits 10-14: Individual-Number • Digits 15-20: Date (YYMMDD)
Swab	• Head material: double layer knitted polyester • Head thermally bonded • Head size: 5.8 (width) x 3 (thickness) x 17 (length) mm • Flat head for easier sampling and streaking on agar • Larger swabbing area • Handle material: polypropylene • Handle size: 3.2 (width) x 75 (length) mm
Ampoule	• Glass ampoule ensuring optimal media protection • Ampoule is sealed and autoclaved immediately after filling with medium • Optimized growth medium for improved neutralization of disinfectants • Double tip ampoule for easy medium release

All-in-one unit	• All-in-one unit containing TSB with neutralizer as growth medium and physiological NaCl solution as moistening liquid
	• Clear packaging
	• Assembled and irradiated in EU
	• Size:
	  ○ Height: 203 mm
	  ○ Diameter of upper part: 12 mm
	  ○ Diameter of plastic skirt: 15 mm
	  ○ Diameter of lower part: 12 mm

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Procedure for sampling of surfaces	• Sampling procedure according to ISO 14698 • Streak the swab in close parallel sweeps over the defined sampling area • Repeat the sampling of the same area by streaking the same swab perpendicular to the initial sweep • After sampling, release the broth medium by breaking the ampoule in the device on both tips **ATTENTION:** break the ampoule first at the bottom and then at the top to optimally release the broth medium and avoid pressing on the ampoule a second time which may cause the formation of glass splinters. Please be aware that even if they appear as particles in the released broth medium, glass splinters do not influence the results of growth promotion and/or sterility tests.
Maintenance of microorganisms on the swab	• It is recommended to release the culture medium from the ampoule into the bottom part of the device as soon as possible after sampling. Storage periods of more than 8 hours should be avoided. The survival of microorganisms on the pre-moistured swab during the time between inoculation of the swab and release of the growth medium from the ampoule into the lower part of the device is highly dependent on the tested strain. The survival of sensitive microorganisms cannot be guaranteed if they are stored on the swab pad for a longer period without growth medium (see validation report).
Incubation	• Incubate the PMM swab vertically as a whole, after releasing the growth medium from the ampoule into the lower part of the device.
Delivery	• Temperature controlled delivery on request • For shipments of larger amounts plastic pallets in Euro-size are used
Place of production	PharmaMedia Dr. Müller GmbH Gustav-Throm-Str. 1, 69181 Leimen - Germany

<table>
<tr><th></th><th>Quality control, Certificates</th></tr>
<tr><td>Certificates</td><td>
Each lot of product can be obtained with a certificate of analysis (CoA):
<table>
<tr><td colspan="5">Physico-chemical test parameters:</td></tr>
<tr><td>Appearance*</td><td colspan="4">Clear, yellowish</td></tr>
<tr><td>pH value*</td><td colspan="4">7.1 – 7.5</td></tr>
<tr><td>Filling volume*</td><td colspan="4">1,800 – 2,200 µL</td></tr>
<tr><td>Irradiation</td><td colspan="4">25 - 45 kGy</td></tr>
<tr><td colspan="5"></td></tr>
<tr><td colspan="5">Growth Promotion test: 10 - 100 CFU</td></tr>
<tr><td>S. aureus</td><td>ATCC 6538</td><td>30 - 35 °C</td><td>≤ 3 days</td><td>Good growth</td></tr>
<tr><td>E. coli</td><td>ATCC 8739</td><td>30 - 35 °C</td><td>≤ 3 days</td><td>Good growth</td></tr>
<tr><td>P. paraeruginosa</td><td>ATCC 9027</td><td>30 - 35 °C</td><td>≤ 3 days</td><td>Good growth</td></tr>
<tr><td>B. spizizenii</td><td>ATCC 6633</td><td>30 - 35 °C</td><td>≤ 3 days</td><td>Good growth</td></tr>
<tr><td>C. albicans</td><td>ATCC 10231</td><td>20 - 25 °C</td><td>≤ 5 days</td><td>Good growth</td></tr>
<tr><td>A. brasiliensis</td><td>ATCC 16404</td><td>20 - 25 °C</td><td>≤ 5 days</td><td>Good growth</td></tr>
<tr><td colspan="5"></td></tr>
<tr><td colspan="5">Neutralizer test: 10 - 100 CFU (plus 20 µL Aerodisin 2000® per 2 mL)</td></tr>
<tr><td>S. aureus</td><td>ATCC 6538</td><td>30 - 35 °C</td><td>20 - 24 h</td><td>Good growth</td></tr>
<tr><td colspan="5"></td></tr>
<tr><td colspan="5">Sterility control</td></tr>
<tr><td colspan="5">≥ 7 days at 30 – 35 °C, no growth</td></tr>
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* these parameters refer to the growth medium in the ampoule.
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<tr><td>Certificate of origin</td><td>
All media lots produced by PMM can be obtained with a Certificate of Origin (CoO). All animal derived raw materials are specified as follows:

Raw material
Tissue
Animal source
Country of origin
Infectivity category (acc. to TSE guideline: EMA/410/01 current version)

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<tr><td>BSE policy</td><td>

In compliance with the current note for guidance on minimizing the risk of transmitting animal spongiform encephalopathy via human or veterinary medicinal products, we check the CoO of raw material in respect to the specified animal source, the country of origin and the infectivity category. We neither store or process ruminant raw materials obtained from high infectivity tissues (IA) nor ruminant raw materials whose animal source originates from countries or regions with an undetermined risk (cat C/GBR IV).

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<tr><th></th><th>Safety Data</th></tr>
<tr><td>Toxic ingredients</td><td>

None

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	Safety Data
Basic composition	• See typical composition
Solvent content	• None
Safety data sheet required	• Not mandatorily required