ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

SCC Accredited CB-P/S OCPS Accrédité CCN

America

C E R T I F I C A T E

No. U8 104082 0005 Rev. 00

Holder of Certificate: **PATH medical GmbH**
Landsberger Str. 65
82110 Germering
GERMANY

Certification Mark:

Product: **General Medical Devices**
Audiometric OAE/AEP screening device

This product was voluntarily tested to the relevant safety requirements referenced on this certificate. It can be marked with the certification mark above. The mark must not be altered in any way. This product certification system operated by TÜV SÜD America Inc. most closely resembles system 3 as defined in ISO/IEC 17067. Certification is based on the TÜV SÜD "Testing, Certification, Validation and Verification Regulations (TCVVR)". TÜV SÜD America Inc. is an OSHA recognized NRTL for USA and a Standards Council of Canada ISO/IEC 17065 accredited Certification body for Canada.

Test report no.: 713380972

Date, 2026-03-10

(Barbara Plötz)

TÜV SÜD America, Inc. • 401 Edgewater Place Suite #500 • Wakefield • MA 01880 • USA

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TÜV SÜD America

C E R T I F I C A T E

No. U8 104082 0005 Rev. 00

Model(s): QScreen

Tested according to:
ANSI/AAMI ES60601-1:2005/A2:2021
CSA C22.2 No. 60601-1:2014/A2:2022-03
CSA C22.2 No. 60601-2-40:2017
CSA C22.2 No. 60601-1-6:2011/A2:2021-08

Parameters:

Rated Input Voltage:	5 VDC
Rated Frequency:	-
Rated Input Power:	1.4 A
Protection against ingress of water and particular matter:	IP30
Applied Part Type:	BF
Protection Class:	During charging: II During intended use: internally powered

Remarks:
The certificate is valid for USA and Canada.
Other countries might have other requirements,
which were not part of this certification.

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