

EC DECLARATION OF CONFORMITY

Manufacturer: **Sivantos GmbH**
Henri-Dunant-Strasse 100
91058 Erlangen
Germany

Brand: **A&M**
Series: **AM-Products**
Type of Device: **e.g. Hearing Aids**
Product Identification: **See next page**

We declare under our sole responsibility that above products are in conformity with the following Directives:

Council Directive 93/42/EEC as amended by Dir. 2007/47/EC (MDD)

Conformity assessment procedure: Annex II without chapter II.4 of 93/42/EEC
Notified Body: TÜV SÜD Product Service GmbH, Notified Body No.: NB 0123
Ridlerstr. 65, 80339 München, Germany
Classification of device: **Class IIa** (according to Annex IX to Council Directive 93/42/EEC)
The products meet the applicable standards and the basic requirements of the Directive 93/42/EEC Annex I.

Council Directive 2011/65/EU (RoHS)

Relevant Harmonized Standards: EN 50581:2012

Council Directive 2014/53/EU (RED)

¹ Applied Standards: EN 300 328 V2.1.1
(with Bluetooth interface) EN 300 330 V2.1.1
² Applied Standards: EN 300 422-4 V2.1.1
(with Telecoil)
³ Applied Standards: EN 300 330 V2.1.1
(with Wireless Function)

Council Directive 2014/30/EU (EMC)

⁴ Applied Standards: EN 301 489-1 V1.9.2
(with Bluetooth interface)
⁵ Applied Standards: EN 55011:2009

Place and valid from date: Erlangen, September 13th, 2018

Name

Klaus Wiggins

(Managing Director)

i.V. Rainer Walther

(Quality Management)

Signature

This declaration will be renewed on any significant change of product, product range, standards and laws.

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Product Identification – RIC (Receiver In the Canal) hearing aid:

XTM RIC P8 ^{2/3}

Demo XTM RIC P8 ^{2/3}

Product Identification – BTE (Behind The Ear) hearing aid:

AM 111 ⁵

Aurora 2 P ⁵

Aurora 2 S ⁵

Aurora 2 XP ⁵

Aurora 4 Pro P ⁵

Aurora 4 Pro Open ⁵

Aurora 4 Pro XP ⁵

Digitrim 12 P ⁵

Digitrim 12 S ⁵

Digitrim 12 XP ⁵

Digitrim 23 P ⁵

Digitrim 23 S ⁵

Digitrim 23 XP ⁵

XTM M P8 ^{2/3}

Demo XTM M P8 ^{2/3}

XTM P P8 ^{2/3}

Demo XTM P P8 ^{2/3}

XTM S P8 ³

Demo XTM S P8 ³

XTM XP P8 ^{2/3}

Demo XTM XP P8 ^{2/3}

XTM M P6 ^{2/5}

XTM P P6 ^{2/5}

XTM S P6 ^{2/5}

XTM XP P6 ^{2/5}

Demo XTM XP P6 ⁵

XTM P P4 ^{2/5}

Demo XTM P P4 ⁵

XTM S P4 ^{2/5}

Demo XTM S P4 ⁵

XTM XP P4 ^{2/5}

Demo XTM XP P4 ⁵

XTM P A4 ⁵

Demo XTM P A4 ⁵

XTM XP A4 ⁵

Demo XTM XP A4 ⁵

STF P T3 ⁵

Demo STF P T3 ⁵

STF XP T3 ⁵

Demo STF XP T3 ⁵

STF P T1 ⁵

Demo STF P T1 ⁵

XTM m P6 ^{2/5}

Demo XTM m P6 ⁵

XTM p P6 ^{2/5}

Demo XTM p P6 ⁵

XTM s P6 ⁵

Demo XTM s P6 ⁵

XTM S A4 ⁵

Demo XTM S A4 ⁵

Product Identification – ITE (In The Ear) Hearing aid:

XTM IF CIC P8 ³

Demo XTM IF CIC P8 ³

XTM IF CIC P6 ⁵

Demo XTM IF CIC P6 ³

XTM IF CIC P4 ⁵

Demo XTM IF CIC P4 ³

XTM IF CIC A4 ⁵

Demo XTM IF CIC A4 ³

XTM IF ITC P6 ⁵

Demo XTM IF ITC P6 ³

XTM IF ITC P4 ⁵

Demo XTM IF ITC P4 ³

XTM IF ITC A4 ⁵

Demo XTM IF ITC A4 ³

Aurora 4 Pro Custom ⁵

XTM Custom P4 ³

Aurora 2 Custom ⁵

XTM Custom P6 ⁵

Digitrim 12 Custom ⁵

XTM Custom P6 a ³

Digitrim 23 custom ⁵

XTM Custom P8 ³

Superscript numbers behind the product name are not part of the product name, but indicate the applicability of the listed standards.