



# EC Certificate

## Full Quality Assurance System

### Directive 93/42/EEC on Medical devices, Annex II excluding section 4

Certificate No.:  
**DGM – 041**

Reference:  
**aur2a1902v690f121**

Date of issue:  
**2019-02-19**

Valid Until:  
**2021-08-24**

Initial date of issue:  
**1997-09-15**

This is to certify that the quality system of:

**Bernafon AG**  
**Morgenstrasse 131**  
**3018 Bern**  
**Switzerland**

has been audited under the requirements of:

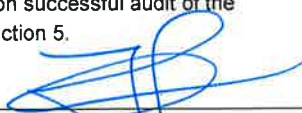
**Annex II, Full quality assurance system, excluding section 4, of Council Directive 93/42/EEC as transposed into Danish law. The quality system meets the requirements of the MDD, Annex II.**

The certificate covers the following devices:

**Design, manufacture and final inspection of BTE hearing aids, ITE hearing aids and accessories in class IIa**

The EC certificate is valid provided that the quality system continues to conform to the above-mentioned scope and provided that the manufacturer does not introduce substantial changes to the quality system without the approval of Presafe Denmark A/S. This EC certificate is issued in accordance with Presafe Denmark A/S' "General terms and conditions" cf. Council Directive 93/42/EEC concerning medical devices and entitles the manufacturer to affix the CE mark. The certificate is based on successful audit of the manufacturer. The manufacturer is subject to periodical audits in accordance with the MDD, Annex II, section 5.

**Presafe Denmark A/S**  
Notified Body, Identification No. 0543  
Tuborg Parkvej 8, 2900 Hellerup, Denmark

  
**Heidi Jørgensen**  
Authorized person  
For Presafe Denmark A/S



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The following BTE hearing aid families in class IIa are covered by the certificate:

<b>ACRIVA 7</b>	<b>ACRIVA 9</b>	<b>BEFLEX</b>
<b>CARISTA 3</b>	<b>CARISTA 5</b>	<b>CHRONOS 5</b>
<b>CHRONOS 7</b>	<b>CHRONOS 9</b>	<b>HEARTOO1</b>
<b>INIZIA 1</b>	<b>INIZIA 3</b>	<b>JUNA 7</b>
<b>JUNA 9</b>	<b>MOVE</b>	<b>Neo</b>
<b>NEVARA 1</b>	<b>OPUS 1</b>	<b>OPUS 2</b>
<b>Prio</b>	<b>SAPHIRA 3</b>	<b>SAPHIRA 5</b>
<b>SUPREMIA 3</b>	<b>SUPREMIA 7</b>	<b>VERAS 5</b>
<b>VERAS 7</b>	<b>VERAS 9</b>	<b>Viron</b>
<b>Win</b>	<b>XTREME</b>	<b>Zerena 9</b>
<b>Zerena 7</b>	<b>Zerena 5</b>	<b>Zerena 3</b>
<b>Zerena 1</b>		

The following ITE hearing aid families in class IIa are covered by the certificate:

<b>ACRIVA 7</b>	<b>ACRIVA 9</b>	<b>CARISTA 3</b>
<b>CARISTA 5</b>	<b>CHRONOS 5</b>	<b>CHRONOS 7</b>
<b>CHRONOS 9</b>	<b>HEARTOO1</b>	<b>INIZIA 1</b>
<b>INIZIA 3</b>	<b>JUNA 7</b>	<b>JUNA 9</b>
<b>MOVE</b>	<b>Neo</b>	<b>NEVARA 1</b>
<b>Prio</b>	<b>SAPHIRA 3</b>	<b>SAPHIRA 5</b>
<b>VERAS 5</b>	<b>VERAS 7</b>	<b>VERAS 9</b>
<b>Win</b>	<b>Zerena 9</b>	<b>Zerena 7</b>
<b>Zerena 5</b>	<b>Zerena 3</b>	<b>Zerena 1</b>



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The following accessories for hearing aid in class IIa are covered by the certificate:

**Remote control**

**OASIS (fitting software)**

**OASIS nxt (fitting software)**

**HEARTOO STUDIO  
(fitting software)**