

This is to certify that the quality system of:

Bernafon AG
Morgenstrasse 131
3018 Bern
Switzerland

has been approved in conformity with the requirements of:

Annex II Full quality assurance system

of Council Directive 93/42/EEC concerning medical devices as amended and transposed into Danish law, excluding Annex II, section 4.

The certificate covers the following activities:

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

This EC certificate is issued in accordance with Presafe Denmark A/S' terms and conditions of, 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 Directive.



Heidi Jørgensen
Authorized person

For Presafe Denmark A/S

Valid from: 2017-05-30
Valid until: 2021-08-24
Initial date of issue: 1997-09-15
Reference: aur2a1705v590f121

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

ACRIVA 7

ACRIVA 9

BEFLEX

CARISTA 3

CARISTA 5

CHRONOS 5

CHRONOS 7

CHRONOS 9

INIZIA 1

INIZIA 3

JUNA 7

JUNA 9

MOVE

Neo

Certificate number: DGM – 041
Certificate type: EC Certificate

Valid from: 2017-05-30
Valid until: 2021-08-24
Initial date of issue: 1997-09-15
Reference: aur2a1705v590f121

NEVARA 1

OPUS 1

OPUS 2

Prio

SAPHIRA 3

SAPHIRA 5

SUPREMIA 3

SUPREMIA 7

VERAS 5

VERAS 7

VERAS 9

Win

XTREME

Zerena 9

Zerena 7

Zerena 5

Certificate number: DGM – 041
Certificate type: EC Certificate

Valid from: 2017-05-30
Valid until: 2021-08-24
Initial date of issue: 1997-09-15
Reference: aur2a1705v590f121

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

ACRIVA 7

ACRIVA 9

CARISTA 3

CARISTA 5

CHRONOS 5

CHRONOS 7

CHRONOS 9

INIZIA 1

INIZIA 3

JUNA 7

JUNA 9

MOVE

Neo

NEVARA 1

Prio

SAPHIRA 3

SAPHIRA 5

VERAS 5

Certificate number: DGM – 041
Certificate type: EC Certificate

Valid from: 2017-05-30
Valid until: 2021-08-24
Initial date of issue: 1997-09-15
Reference: aur2a1705v590f121

VERAS 7

VERAS 9

Win

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

Remote control

OASIS (fitting software)

OASIS nxt (fitting software)

Certificate number: DGM – 041
Certificate type: EC Certificate

Valid from: 2017-05-30
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