EC Certificate

Certificate Number: DGM – 001

This is to certify that the quality system of:

Oticon A/S
Kongebakken 9
2765 Smørum
Denmark

has been approved in conformity with the requirements of:

Annex II, section 3.2 - Full quality assurance system

of Council Directive 93/42/EEC concerning medical devices as 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, pocket hearing aids and accessories for hearing aids 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 company does not introduce substantial changes to the quality system without the approval of Presafe Denmark A/S. This EC certificate is issued pursuant to the Presafe Denmark A/S' terms and conditions for the certification of 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 as per the Directive.

Heidi Jørgensen
Authorized person

For Presafe Denmark A/S

Date of issue:	2014-01-14
Expires:	2018-07-14
Initial date of issue:	1996-01-25
Reference:	aur2a1312v840f013

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

DGM

DANISH MEDICAL
DEVICES CERTIFICATION

Quality System Certificate

DGM – 640

This is to certify that the quality system of

Oticon A/S
Kongebakken 9
2765 Smørum
Denmark

fulfills the requirements in

DS/EN ISO 9001:2008 and DS/EN ISO 13485:2012

The scope of the certificate is:

Development, production, sales and service of audiological solutions for better hearing

The certificate is valid provided that the quality system continues to conform to the above-mentioned scope and provided that the company does not introduce substantial changes to the quality system without the approval of DGM Denmark A/S. Certifications to DS/EN ISO 13485:2012, EN ISO 13485:2012, ISO 13485:2003, DS/EN ISO 9001: 2008, EN ISO 9001:2008 and ISO 9001:2008 include the requirements of the valid corrigenda. The quality system certificate is issued pursuant to the DGM Denmark A/S rules for the certification of quality systems for medical devices.

Bent Buus
Authorized person

Valid from:	2013-07-16
Valid until:	2016-07-14
Initial date of issue:	2008-09-24
Reference:	aur2a1303v801f013

DGM Denmark A/S

Notified Body, Identification No. 0543

Tuborg Parkvej 8, DK-2900 Hellerup - Denmark

DANAK
SYSTEM Reg. No. 5007

Presafe
A DNV & NEMKO COMPANY

DGM

DANISH MEDICAL
DEVICES CERTIFICATION

Additional sites covered by the certificate:

Tempovej 15 **DK-2750 Ballerup** **Denmark**
Tilstedvej 73 **DK-7700 Thisted** **Denmark**
Oticon Polska Production Sp. zo. o. **ul. Lubieszyńska 59, Mierzyn** **72-006 Szczecin** **Poland**

Certificate number:	DGM – 640	Valid from:	2013-07-16
Certificate type:	Quality System Certificate	Valid until:	2016-07-14
		Initial date of issue:	2008-09-24
		Reference:	aur2a1303v801f013

DANAK
SYSTEM Reg. No. 5007

Presafe
A DNV & NEMKO COMPANY