



Quality System Certificate

Certificate Number: 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 certificate covers the following activities:

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 Presafe 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 applicable corrigenda. The quality system certificate is issued pursuant to Presafe Denmark A/S' terms and conditions for the certification of quality systems for medical devices.


Heidi Jørgensen
Authorized person

For Presafe Denmark A/S

Date of issue: 2013-11-12
Expires: 2016-07-14
Initial date of issue: 2008-09-24
Reference: aur2a1311v830f013

Presafe Denmark A/S

Tuborg Parkvej 8
2900 Hellerup
Denmark



DGM

Additional sites covered by the certificate:

**DGS Ballerup
Tempovej 15
2750 Ballerup
Denmark**

**DGS Thisted
Tilstedvej 73
7700 Thisted
Denmark**

**DGS Poland Sp. zo. o.
ul. Lubieszńska 59, Mierzyn
72-006 Szczecin
Poland**

**DGS Poland Sp. zo. o.
ul. Lubieszńska 42, Mierzyn
72-006 Szczecin
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