



# Quality System Certificate

Certificate Number: DGM – 650

This is to certify that the quality system of:

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

fulfills the requirements in:

**EN ISO 13485:2016**

The certificate covers the following activities:

**Development, production, marketing, 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 13485:2016, EN ISO 13485:2016, ISO 13485:2016, and ISO 9001:2015 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: 2018-11-09  
Expires: 2021-09-27  
Initial date of issue: 2008-09-24  
Reference: aur2a1810v662f121

**Presafe Denmark A/S**

Tuborg Parkvej 8  
2900 Hellerup  
Denmark



Additional sites covered by the certificate:

**Oticon A/S**  
Kongebakken 9  
2765 Smørum  
Denmark

**DGS Denmark A/S**  
Tempovej 15  
2750 Ballerup  
Denmark

**DGS Poland Sp. z o. o.**  
ul. Lubieszńska 59 and 42  
72-006 Mierzyn  
Poland

**DGS Poland Sp. z o. o.**  
ul. Wiosenna 5  
72-006 Mierzyn  
Poland

**Demant Technology Centre Sp. z o.o.**  
Q22, Al. Jana Pawła II 22, 9<sup>th</sup> Floor  
00-133 Warszawa  
Poland

**DGS Business Services Sp. z o. o.**  
ul. Malczewskiego 26  
71-612 Szczecin  
Poland.

**DGS Tijuana**  
Boulevard Héctor Terán Terán 2102  
Tijuana, BC 22203  
Mexico

**Oticon Inc.**  
580 Howard Avenue  
Somerset, NJ 08873  
USA

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