



Certificate

No. Q5 058366 0002 Rev. 01

Holder of Certificate: **Oticon A/S**
Kongebakken 9
2765 Smørum
DENMARK

Certification Mark:



Scope of Certificate: **Design and development, production, distribution, sales and service of hearing aids and software solutions for hearing incl. apps**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 058366 0002 Rev. 01

Report No.: 713197068

Valid from: 2021-03-15
Valid until: 2023-08-12

Date, 2021-03-15

Christoph Dicks
Head of Certification/Notified Body

Digitally signed by Mojila Violetta
Date: 2022.05.27 17:32:32 EEST
Reason: MoldSign Signature
Location: Moldova



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Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Oticon A/S
Kongebakken 9, 2765 Smørum, DENMARK

Design, development, purchasing, management (RA), monitoring
and measurement

DGS Denmark A/S
Tempovej 15, 2750 Ballerup, DENMARK

Production

DGS Poland Sp. z o.o.
ul. Lubieszynska 59, 42, 72-006 Mierzyn, POLAND

Production, final inspection and testing

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

Warehouse

Demant Technology Centre Sp. z o.o.
Q22, Al. Jana Pawla II, 9th Fl., 00-133 Warszawa, POLAND

Design and development of software

DGS Business Services Sp. z o.o.
ul. Malczewskiego 26, 71-612 Szczecin, POLAND

Support of design and development

Oticon Inc
580 Howard Avenue, Somerset NJ 08873, USA

Production, final inspection and testing

DGS Tijuana
Boulevard Hector Teran, 2102, Edificio 1, Canon del Padre, 22203
Tijuana, MEXICO

Production, final inspection and testing

Demant Operations, S.A. de C.V.
Boulevard Corredor Tijuana-Rosarito 2000, #24702 H-1, Ejido
Francisco Villa, 22235 Tijuana Baja California, MEXICO

Production, final inspection and testing