

Quality System Certificate

Certificate No.:
DGM – 913

Reference:
aurISO1806v30f845

Date of issue:
2018-12-28

Valid Until:
2021-12-28

Initial date of issue:
2018-12-28

This is to certify that the quality system of:

Visiopharm A/S
Agern Allé 24
2970 Hørsholm
Denmark

fulfills the requirements in:

EN ISO 13485:2016

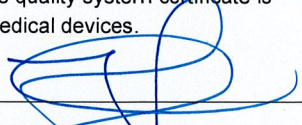
The certificate covers the following activities:

Design, development, manufacture, installation and service of in vitro diagnostic pathology software

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, DS/EN ISO 9001:2015, EN ISO 9001:2015, and ISO 9001:2015 include the requirements of any applicable corrigendum. The quality system certificate is issued pursuant to Presafe Denmark A/S' terms and conditions for the certification of quality systems for medical devices.

Presafe Denmark A/S

Notified Body, Identification No. 0543
Tuborg Parkvej 8, 2900 Hellerup, Denmark


Heidi Jørgensen
Authorized person

For Presafe Denmark A/S