

# Quality System Certificate

Certificate No.:  
**DGM – 816**

Reference:  
**aur1i1906v91f813**

Date of issue:  
**2019-11-05**

Valid Until:  
**2020-06-23**

Initial date of issue:  
**2014-07-17**

This is to certify that the quality system of:

**Ambi Pack BV**  
**De Zelling 17**  
**3342 GS Hendrik-Ido-Ambacht**  
**The Netherlands**

fulfills the requirements in:

**DS/EN ISO 13485:2016**

The certificate covers the following activities:

**Mixing, tableting, capsulating and packaging of oral and topical administered products registered as medical devices**

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

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## Additional sites covered by the certificate:

Ambi Pack BV  
De Zelling 1  
3342 GS Hendrik-Ido-Ambacht  
The Netherlands

Ambi Pack BV  
Het Tasveld 3  
3342 GT Hendrik-Ido-Ambacht  
The Netherlands

Ambi Pack BV  
Het Tasveld 6  
3342 GT Hendrik-Ido-Ambacht  
The Netherlands

Ambi Pack BV  
Het Tasveld 22  
3342 GT Hendrik-Ido-Ambacht  
The Netherlands

Ambi Pack BV  
Het Tasveld 24  
3342 GT Hendrik-Ido-Ambacht  
The Netherlands

Ambi Pack BV  
Het Tasveld 26  
3342 GT Hendrik-Ido-Ambacht  
The Netherlands

Ambi Pack BV  
dePlaats 10  
3342 GL Hendrik-Ido-Ambacht  
The Netherlands