

# MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:  
10000498888-PA-NA-DNK

Initial certification date:  
17 July 2014  
(By different CB)

Valid:  
11 March 2022 – 22 June 2023

This is to certify that the management system of  
**Ambi Pack B.V.**  
Zelling 17, 3342 GS Hendrik-Ido-Ambacht, Netherlands  
and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:  
**ISO 13485:2016**

This certificate is valid for the following scope:

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

Place and date:  
Høvik, 11 March 2022



For the issuing office:  
DNV Product Assurance AS  
Veritasveien 3, 1363 Høvik, Norway

*Cecilie Gudesen Torp*

Cecilie Gudesen Torp  
Management Representative

## Appendix to Certificate

### Ambi Pack B.V.

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
Ambi Pack B.V.	Zelling 17, 3342 GS Hendrik-Ido-Ambacht, Netherlands	Mixing, tableting, capsulating and packaging of oral and topical administered products registered as medical devices
Ambi Pack B.V. - Operative Site	De Zelling 1, 3342 GS Hendrik-Ido-Ambacht, Netherlands	Mixing, tableting, capsulating and packaging of oral and topical administered products registered as medical devices
Ambi Pack B.V. - Operative Site	Het Tasveld 6, 3342 GT Hendrik-Ido-Ambacht, Netherlands	Mixing, tableting, capsulating and packaging of oral and topical administered products registered as medical devices
Ambi Pack B.V. - Operative Site	Het Tasveld 3, 3342 GT Hendrik-Ido-Ambacht, Netherlands	Mixing, tableting, capsulating and packaging of oral and topical administered products registered as medical devices
Ambi Pack B.V. - Operative site	Het Tasveld 22, 3342 GT Hendrik-Ido-Ambacht, Netherlands	Mixing, tableting, capsulating and packaging of oral and topical administered products registered as medical devices
Ambi Pack B.V. - Operative Site	Het Tasveld 24, 3342 GT Hendrik-Ido-Ambacht, Netherlands	Mixing, tableting, capsulating and packaging of oral and topical administered products registered as medical devices
Ambi Pack B.V. - Operative Site	Het Tasveld 26, 3342 GT Hendrik-Ido-Ambacht, Netherlands	Mixing, tableting, capsulating and packaging of oral and topical administered products registered as medical devices
Ambi Pack B.V. - Operative Site	De Plaats 10, 3342 GL Hendrik-Ido-Ambacht, Netherlands	Mixing, tableting, capsulating and packaging of oral and topical administered products registered as medical devices