

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