

Certificate

mdc medical device certification GmbH
certifies that

**SOFT
HALE**

Soft hale NV
Bioville, Agoralaan - Building Abis
3590 Diepenbeek
Belgium

for the scope

**design and development of
inhaler devices and associated components**

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system
meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems –
Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

Valid from	2021-07-16
Valid until	2024-07-15
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Head of Certification Body

