

DEKRA Certification B.V.

STATUS QUO DECLARATION

Date: 27 September 2018

Manufacturer:

Koninklijke Utermöhlen N.V.
Also trading as Royal Utermöhlen
De Overweg 1
8471 ZA Wolvega
P.O. Box 3
8470 AA Wolvega
The Netherlands

To Whom It May Concern,

DEKRA Certification B.V. in its capacity of Notified Body for Medical Devices, declares the following:

DEKRA performed on May 15-16 2018 a Renewal and Upgrade audit for the EN ISO 13485:2016, combined with the audit for Renewal for CE marking (MDD). The report is currently in the final reporting phase.

It is noted that **no** Major NCs are hindering a positive recommendation towards the issuance of the renewed ISO and CE certificates. The Minor NCs issued and the Follow up in the CAPA Plans and verification of effectiveness do **not** hinder a positive recommendation.

A regular certification validity term is recommended: for the ISO certificate: 3 years and for the MDD CE cert of 5 years.

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Drs. G. Buijzen