

Declaration of Conformity

We,

**DenTek Oral Care Limited, of Clockhouse Court, 5-7 London Road
St Albans, Herts. AL1 1LA**

Hereby declare in our own responsibility as the legal manufacturer that the medical device product family -

Doctor's Night Guard family of products, marketed with names

**Doctor's NightGuard Advanced Comfort
Ekulf NightGuard
Grindguard Advanced Comfort
Sleepzz Anti-Tandenknars Gebitsbeschermer**

are in compliance with Annex VII of Council Directive 93/42/EC, concerning medical devices, as amended by Directive 2007/47/EC

Conformity assessment procedure:

According to Annex VII of the Directive named above

Device Classification:

According to Annex IX of the Directive named above

Class I, rule 5

Self-certified

Every medical device specimen manufactured according to the current product Technical File, and obtained from standard batches, identified by lot number and manufacturing date, conforms to the Essential Requirements as stated in Annex II of the Medical Devices Directive 93/42/EC, as amended.

We also commit to initiate and keep up to date a systematic procedure to review experience gained on our medical devices in the postproduction phase, to implement appropriate means to apply any necessary corrective action and to notify the relevant Competent Authorities of each and every reportable event.

This Declaration of Conformity is valid until 2021-05-20.

Signed:  Date: 

Mr Andy Wines
General Manager