



# EC CERTIFICATE

## Full Quality Assurance System

Certificate no.:  
242005-2017-CE-IND-NA-PS

Initial certification date:  
19 June 2017

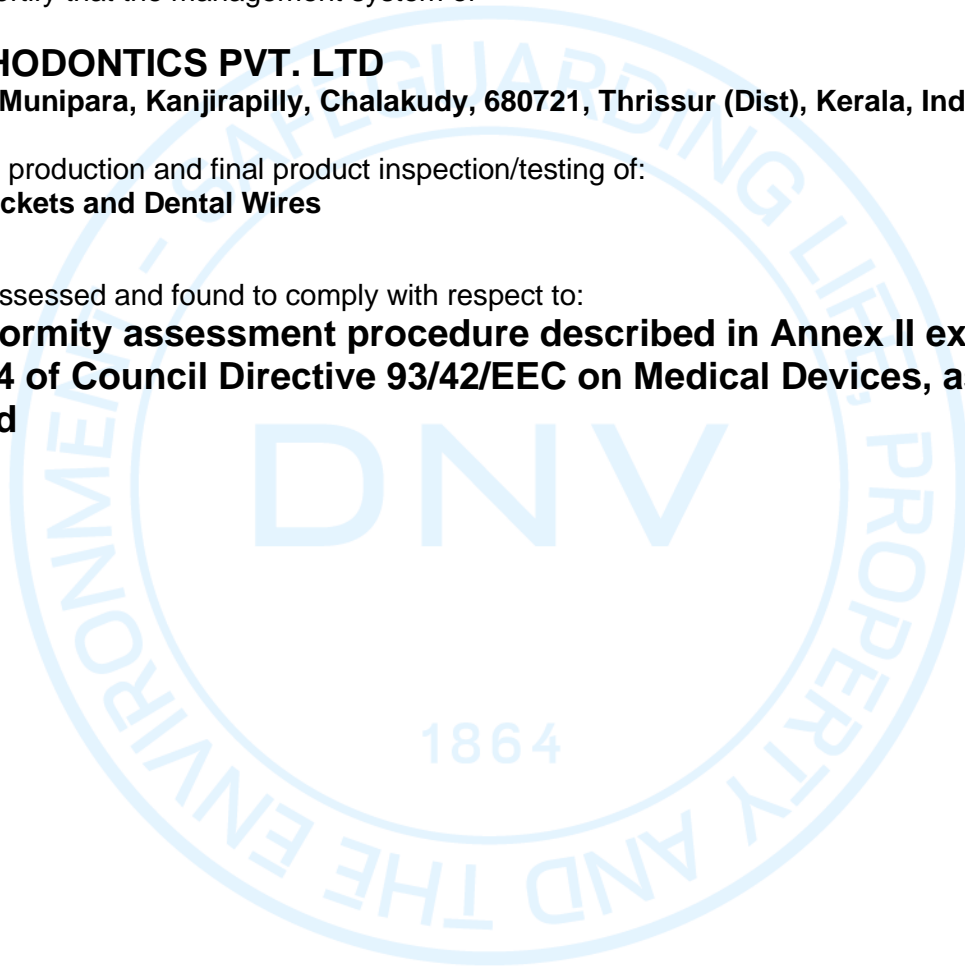
Valid Until:  
19 June 2022

This is to certify that the management system of

**JJ ORTHODONTICS PVT. LTD**  
VII /202 E, Munipara, Kanjirapilly, Chalakudy, 680721, Thrissur (Dist), Kerala, India

For design, production and final product inspection/testing of:  
**Dental Brackets and Dental Wires**

has been assessed and found to comply with respect to:  
**the conformity assessment procedure described in Annex II excluding section 4 of Council Directive 93/42/EEC on Medical Devices, as amended**



Place and date:  
Høvik, 22 May 2021

For the issuing office:  
DNV Product Assurance AS - Notified Body  
2460  
Veritasveien 3, 1363 Høvik, Norway



**Veena Gunashekaran**

## Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window

## Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.