

## EU Declaration of Conformity for medical devices

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We, the manufacturer

**NTI-Kahla GmbH**  
**Rotary Dental Instruments,**

Im Camisch 3,  
D-07768 Kahla/Germany,

*declare in sole  
responsibility that  
the medical devices  
of the product group*

***Diamond finishing strips***

comply with the  
**intended purpose**

dental application

and Risk Class

**I**

after conducting  
a conformity  
assessment procedure  
according to

Regulation (EU) 2017/745, Article 52, Section 7

*with regard to all applicable requirements of Regulation (EU) 2017/745, in particular the Annexes I, II and III. The Declaration of Conformity applies to all medical devices listed in the Annex.*

This Declaration of Conformity is valid from 26.05.2021. The validity is limited to 26.05.2025. In case of changes to the medical devices, to the certification status of the quality management system or when a new EU Declaration of Conformity is issued, this issue also loses its validity.

Kahla, dated 26.05.2021



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Wolfgang Lenkner  
CEO

## EU Declaration of Conformity for medical devices

| Article name/group       | NTI Article No. (REF) | MDR-Class | MDR-Rule | Scope   | CE Marking | UMDNS Code | GMDN Code |
|--------------------------|-----------------------|-----------|----------|---------|------------|------------|-----------|
| Diamond finishing strips | FS2-F                 | I         | 5        | MD 0401 | CE         | 11-160     | 63358     |
| Diamond finishing strips | FS6-SF                | I         | 5        | MD 0401 | CE         | 11-160     | 63358     |
| Diamond finishing strips | FS2-M                 | I         | 5        | MD 0401 | CE         | 11-160     | 63358     |
| Diamond finishing strips | FS2-SF                | I         | 5        | MD 0401 | CE         | 11-160     | 63358     |
| Diamond finishing strips | FS3-F                 | I         | 5        | MD 0401 | CE         | 11-160     | 63358     |
| Diamond finishing strips | FS3-FX                | I         | 5        | MD 0401 | CE         | 11-160     | 63358     |
| Diamond finishing strips | FS3-M                 | I         | 5        | MD 0401 | CE         | 11-160     | 63358     |
| Diamond finishing strips | FS3-MX                | I         | 5        | MD 0401 | CE         | 11-160     | 63358     |
| Diamond finishing strips | FS3-SF                | I         | 5        | MD 0401 | CE         | 11-160     | 63358     |
| Diamond finishing strips | FS3-SFX               | I         | 5        | MD 0401 | CE         | 11-160     | 63358     |
| Diamond finishing strips | FS3-X-SO              | I         | 5        | MD 0401 | CE         | 11-160     | 63358     |
| Diamond finishing strips | FS6-F                 | I         | 5        | MD 0401 | CE         | 11-160     | 63358     |
| Diamond finishing strips | FS6-M                 | I         | 5        | MD 0401 | CE         | 11-160     | 63358     |
| Diamond finishing strips | FS3-MP                | I         | 5        | MD 0401 | CE         | 11-160     | 63358     |
| Diamond finishing strips | FS3-FP                | I         | 5        | MD 0401 | CE         | 11-160     | 63358     |
| Diamond finishing strips | FS3-SFP               | I         | 5        | MD 0401 | CE         | 11-160     | 63358     |
| Diamond finishing strips | FS3-MXP               | I         | 5        | MD 0401 | CE         | 11-160     | 63358     |
| Diamond finishing strips | FS3-FXP               | I         | 5        | MD 0401 | CE         | 11-160     | 63358     |
| Diamond finishing strips | FS3-SFXP              | I         | 5        | MD 0401 | CE         | 11-160     | 63358     |
| Diamond finishing strips | FS2-MP                | I         | 5        | MD 0401 | CE         | 11-160     | 63358     |
| Diamond finishing strips | FS2-FP                | I         | 5        | MD 0401 | CE         | 11-160     | 63358     |
| Diamond finishing strips | FS2-SFP               | I         | 5        | MD 0401 | CE         | 11-160     | 63358     |
| Diamond finishing strips | FS6-FP                | I         | 5        | MD 0401 | CE         | 11-160     | 63358     |
| Diamond finishing strips | FS6-SFP               | I         | 5        | MD 0401 | CE         | 11-160     | 63358     |
| Diamond finishing strips | FS6-MP                | I         | 5        | MD 0401 | CE         | 11-160     | 63358     |
| Diamond finishing strips | FS6-SO                | I         | 5        | MD 0401 | CE         | 11-160     | 63358     |
| Diamond finishing strips | FS3-P-SO              | I         | 5        | MD 0401 | CE         | 11-160     | 63358     |
| Diamond finishing strips | FS3-XP-SO             | I         | 5        | MD 0401 | CE         | 11-160     | 63358     |
| Diamond finishing strips | FS5-MKP               | I         | 5        | MD 0401 | CE         | 11-160     | 63358     |
| Diamond finishing strips | FS5-FKP               | I         | 5        | MD 0401 | CE         | 11-160     | 63358     |
| Diamond finishing strips | FS5-SFKP              | I         | 5        | MD 0401 | CE         | 11-160     | 63358     |
| Diamond finishing strips | FS5-XKP               | I         | 5        | MD 0401 | CE         | 11-160     | 63358     |
| Diamond finishing strips | FS5-KP-SO             | I         | 5        | MD 0401 | CE         | 11-160     | 63358     |
| Diamond finishing strips | FSG-1                 | I         | 5        | MD 0401 | CE         | 11-160     | 63358     |