

CERTIFICAT
CERTIFICATE OF REGISTRATION
BESCHEINIGUNG
N° 10026 rev. 4

Le LNE certifie que le système de management de la qualité développé par
LNE certifies that the quality management system developed by
LNE bescheinigt, daß das Qualitäts-Management-System von

MAILLEFER INSTRUMENTS HOLDING S.A.R.L.
3 chemin du Verger
1338 BALLAIGUES SWITZERLAND

pour les activités / for the activities / für die Tätigkeiten

Conception, fabrication et commercialisation d'instruments et systèmes stériles ou non stériles destinés à l'art dentaire. Fabrication d'instruments non stériles pour la chirurgie et l'implantologie dentaire et orthopédique (voir détails sur addendum)

Development, manufacturing and marketing of instruments and devices, sterile or non-sterile, in dental use. Manufacturing and marketing of non sterile instruments for surgery and dental implantology as well as for orthopaedic applications (see details on addendum)

Herstellung und Vertrieb von Dentalinstrumenten- und Systemen - steril und nicht steril. Herstellung und Vertrieb von nicht sterilen Instrumenten für die Chirurgie und Implantologie (dental und orthopädisch) (Details im Addendum)

réalisées sur le(s) site(s) performed on the location(s)/ die im nachstehenden Werk

Voir addendum / See addendum / siehe addendum

est conforme aux exigences des normes internationales
complies with the requirements of the international standards
den Anforderungen der internationalen Normen entspricht

NF EN ISO 13485 : 2012

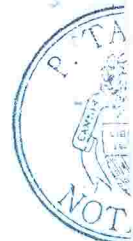
Début de validité / Effective date / Gültigkeitsanfang July 9th, 2015 (included)
Valable jusqu'au / Expiry date / Gültigkeitsende July 8th, 2018 (included)
Etabli le / Issued on/ Ausstellungsdatum June 8th, 2015



On behalf of the Deputy Director
Cécile AUGELADE
G-MED Certification Division Manager
der stellvertretende Direktor i.V.



LNE N° 10026-N° 4
Ce certificat est délivré selon les règles de certification G-MED / This certificate is issued according to the rules of G-MED certification / LNE/G-MED Notified Body for Medical Devices
Renouvelle le certificat 10026-3



Ce certificat couvre les entités suivantes:

This certificate covers the following entities:

MAILLEFER INSTRUMENTS HOLDING SARL

And its affiliates:

- Maillefer Instruments Trading Sarl
 - Maillefer Instruments Manufacturing Sarl
 - Maillefer Instruments Consulting Sarl
- Trading as "Dentsply Maillefer"**
Chemin du verger 3
1338 Ballaigues
Switzerland

pour les activités suivantes / for the following activities / für die Tätigkeiten :

Version française :

Conception, fabrication et commercialisation d'instruments et systèmes stériles ou non stériles destinés à l'art dentaire pour l'organisation, le diagnostic, le nettoyage, la mise en forme, l'irrigation, l'obturation et la reconstitution.

Fabrication d'instruments non stériles pour la chirurgie et l'implantologie dentaire et orthopédique.

Version anglaise :

Development, manufacturing and marketing of instruments and devices, sterile or non-sterile, for organization, diagnosis, cleaning, shaping, irrigation, obturation and reconstruction in dental use.

Manufacturing and marketing of non-sterile instruments for surgery and dental implantology as well as for orthopaedic applications.

Version allemande :

Herstellung und Vertrieb von Dentalinstrumenten- und Systemen - steril und nicht steril - zur Organisation, Diagnose, Reinigung, Aufbereitung, Irrigation, Füllung und Wiederaufbau.

Herstellung und Vertrieb von nicht sterilen Instrumenten für die Chirurgie und Implantologie (dental und orthopädisch).



On behalf of the Deputy Director-
Cécile VAUGELADE
G-MED Certification Division Manager

pour les sites suivants / for the following facilities / die im nachstehenden Werke :

- **Chemin du Verger, 3, 1338 BALLAIGUES, SUISSE :**

Development, manufacturing and marketing of instruments and devices, sterile or non-sterile, for organization, diagnosis, cleaning, shaping, irrigation, obturation and reconstruction in dental use. Manufacturing and marketing of non-sterile instruments for surgery and dental implantology as well as for orthopaedic applications.

- **Chemin de Beau-Site, 5, 1338 BALLAIGUES, SUISSE :**

Manufacturing of instruments and devices, sterile or non-sterile, for organization, diagnosis, cleaning, shaping, irrigation, obturation and reconstruction in dental use. Manufacturing of non-sterile instruments for surgery and dental implantology as well as for orthopaedic applications.

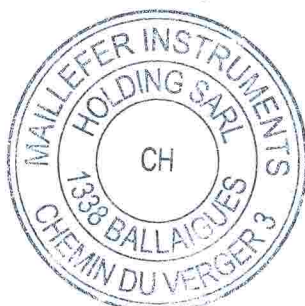
- **Le Creux, 1338 BALLAIGUES, SUISSE :**

Manufacturing of instruments and devices, sterile or non-sterile, for organization, diagnosis, cleaning, shaping, irrigation, obturation and reconstruction in dental use. Manufacturing of non-sterile instruments for surgery and dental implantology as well as for orthopaedic applications.

3 sites / 3 facilities / 3 Werke

Ballaigues, January 19th 2017

Maillefer Instruments Holding Sarl



*Pierre Graf
CFO*



**On behalf of the Deputy Director
Cécile VAUGELADE
G-MED Certification Division Manager**

