

# EU Certificate

for the assessment of the  
quality management system



## according to Medical Device Regulation (EU) 2017/745 Annex IX Chapter I+III

As a Notified Body of the European Union DEKRA Certification GmbH certifies, that the  
manufacturer

**bonyf AG**

**Single Registration Number (SRN): LI-MF-000000739**

Heiligkreuz 16, 9490 Vaduz, Liechtenstein

applies a quality management system according to Annex IX Chapter I+III of the Medical Device Regulation (EU) 2017/745 for the medical devices listed in the annex. This certificate is based on the assessments listed in CNo50537-00 and is only valid in conjunction with the successful completion of the annual surveillance audits.

EU Certificate no.: 50537-60-00-01

Certificate valid from:

2025-02-12

Certificate valid to:

2027-04-18

Previous certificate no. 50537-60-00-00, issued on 2024-11-26



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://www.zlg.de)

BS-MDR-092

DEKRA Certification GmbH, Stuttgart  
Notified Body ID number: 0124

# Annex to the EU Certificate no. 50537-60-00-01

Following devices/device categories are included in this certificate:

## Annex IX

### Class IIa

- MDN 1213
  - Basis UDI-DI: 7611645PE1400JJ  
Basis UDI-DI: 7611645AP0700GG  
Basis UDI-DI: 7611645RE0600KF  
Basis UDI-DI: 7611645OL0500LG  
Basis UDI-DI: 7611645OL0400LB  
Basis UDI-DI: 7611645SU0300QV
    - PerioTabs -Gum and teeth brushing solution
    - AphtoFix- Mouth Ulcer Cream
    - Denture Relining cushion Stabilizer
    - OlivaFix Gold - Denture Adhesive Cream
    - OlivaFix Regular/Fresh - Denture Adhesive Cream
    - Denture Adhesive Cream Superior

### only annex IX

### Class IIb

- MDN 1211
  - Basis UDI-DI: 7611645NI0200JK
    - NitrAdine® Disinfecting Tablets  
NitrAdine® disinfecting tablet is intended to disinfect removable dental appliances such as dentures, orthodontic appliances, anti-snoring devices and anti-bruxism devices

Change to previous certificate: Addition of the product group MDN 1213