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.: 50537-60-00-02

Certificate valid from: 2025-09-17
Certificate valid to: 2027-04-18

Previous certificate no. 50537-60-00-01, issued on 2025-02-12

Digitally signed by Markus RAINER Kopf
Date: 2025-09-17 16:50:47+02:00

Markus Kopf
DEKRA Certification GmbH, Stuttgart
Notified Body ID number: 0124

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-092

Annex to the EU Certificate no. 50537-60-00-02

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
    Basis UDI-DI: 7611645PC1800JG
    - 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
      PerioCream Periodontal Paste

only annex IX

Class IIb

- MDN 1211
  - Basis UDI-DI: 47611645NI0200JK
    - 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: PerioCream Periodontal Paste