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, 90118029-00 and is only valid in conjunction with the successful completion of the annual surveillance audits.

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

Certificate valid from: 2024-11-26
Certificate valid to: 2027-04-18

Digital unterschrieben von
Stephanie Donner
Datum: 2024-11-26 16:28:50+01:00

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

DEKRA Certification GmbH, Stuttgart 2024-11-26
Notified Body ID number: 0124

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

Following devices/device categories are included in this certificate:

Annex IX or XI part A

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