

EU DECLARATION OF CONFORMITY

Name and address of the manufacturer:

ALPRO MEDICAL GMBH
Mooswiesenstr. 9, 78112 St. Georgen • GERMANY

SRN: DE-MF-000010603

Name of the product:

Planmeca PlanPure™

Distributed by:

Planmeca Oy
Asentajankatu 6, 00880 Helsinki • FINLAND

REF: REF 10038303; included in REF 10038859

Basic UDI-DI: ++E251002001006Q

EMDN / CND Code: D0299 - BIGUANIDES FOR THE DISINFECTION OF MEDICAL DEVICES - OTHER

GMDN Code: 47631 - Medical device disinfection agent

Intended purpose of the product:

Ready-to-use-solution for cleaning, disinfection and long-term inhibition of biofilm formation in dental unit waterlines.

Risk class of the product: IIa

Classification rule: 15

Marking of the product:  0123

ALPRO MEDICAL GMBH is manufacturer of the above-mentioned medical device and declares in accordance with Article 120(3), (3a) letter (b) and (3c) of Regulation (EU) 2017/745 and under sole responsibility that this medical device continues to comply with the relevant provisions, in particular with the essential requirements of Annex I of Directive 93/42/EEC and that a complete documentation is available. The conditions of Article 120(3d) of Regulation (EU) 2017/745 are met.

Applied common specifications: n/a

Notified Body:

TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 München • GERMANY

Conformity assessment procedure:

According to Directive 93/42/EEC, Annex II without Section 4

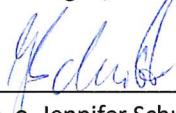
EC Certificate No: G1 029056 0067 Rev. 00

Valid until: 2023-12-31 (extended validity in accordance with Regulation (EU) 2023/607)

This declaration of conformity is valid until: 2028-12-31


ALPRO MEDICAL GMBH

St. Georgen, 20.12.2023


p. o. Jennifer Schuster
PRRC

