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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: CE 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®

ALPRO MEDICAL GMBH

St. Georgen, 20.12.2023

p. o. Jennifer Schuster

PRRC

Qualitätsmanagement QM ALPRO MEDICAL GMBH