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:

bepro suction CM

Distributed by:

W&H Sterilization Srl Via Bolgara 2, 24060 Brusaporto (BG) • ITALY

REF: REF 19500253

Basic UDI-DI: ++E251000605028Q

EMDN / CND Code: V0799 - PRODUCTS FOR CLEANING MEDICAL DEVICES NOT INCLUDED **IN OTHER CLASSES - OTHER**

GMDN Code: 63385 - Medical device cleaning agent

Intended purpose of the product:

Liquid concentrate for the weekly acid contra-cleaning and maintenance of dental aspiration systems with and without amalgam separator.

Risk class of the product: I

Classification rule: 1

Marking of the product: CE

ALPRO MEDICAL GMBH is manufacturer of the above-mentioned medical device and declares under sole responsibility that this medical device complies with the general safety and performance requirements of Regulation (EU) 2017/745 and that a complete documentation is available.

Applied common specifications: n/a

Conformity assessment procedure: According to Regulation (EU) 2017/745, Annex IV

The quality assurance system of ALPRO MEDICAL GMBH is certified according to DIN EN ISO 13485:2016.

This declaration of conformity is valid until: 2024-12-31

ALPRO MEDICAL GMBH

St. Georgen, 11.05.202

Klaus Grensing

QM