REGEDENT
smart regeneration

Manufacturer's Declaration of Conformity

The devices listed in this declaration:

- comply with the applicable General Safety and Performance Requirements in Annex I of Medical Device Regulation 745/2017 (amended by the Commission Regulation (EU) 2020/561; hereafter referred to as 'MDR') regarding medical devices;
- have been classified according to the classification rules of Annex VIII of the MDR regarding medical devices.

The conformity of the devices listed is declared after drawing up the technical documentation set out in Annex II and III of the MDR.

Product Identification

Article Number	0131.401
Product	**PERISOLV** Oral Debridement Gel
Intended Purpose	Indications for Use: PERISOLV is indicated for patients diagnosed with of periodontitis, mucositis or peri-implantitis. Intended Use: PERISOLV is intended to be used non-surgically as a supplementary treatment, applied before debridement, to precondition the treatment site to enable oral tissue regeneration. PERISOLV is a gel in-tended for softening and degrading of biofilm in periodontal and peri-implant pockets.
Standards applied	List of Applied Standards – Perisolv, ID No. PS_List Appl Stand
Basic UDI	D7400131
UDI-DI	Unit of Use: +D74001314010 Shelf Box (containing 5 Units of Use): +D74001314015 Transport Box (containing 10 Shelf Boxes):+D74001314018
GMDN Code	45235
Term	Dental Scaling Solution

Classification

After following the classification rules of Annex VIII of the MDR regarding medical devices, the device listed in this declaration was classified as Class I; rule 5 applies to PERISOLV.

Conformity Assessment

According to the MDR Article 52, based on the classification of the product, the manufacturer, in order to affix the CE marking, declared the conformity after drawing up the technical documentation set out in Annex II and III.

Manufacturer

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Authorized Representative

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This declaration of conformity is issued under the sole responsibility of the manufacturer indicated above.

If the device is modified in any way without the formal approval of the undersigned, this declaration of conformity becomes invalid.

This Declaration of Conformity is
valid from: May 26th, 2021
valid until: May 25th, 2026.

Declaration Approval

on behalf of the legal manufacturer

Zurich, May 10th, 2021

Lucia Calvi
CEO
REGEDENT AG

Place Date