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DECLARATION OF CONFORMITY (MDR)

Certificate No: 22012402Manufacturer:Permatter LLCAddress:175 SW 7th St, Ste 1517, Miami, FL 33130, USA,e-mail:info@permatter.comweb:permatter.com



Product Name: **Permatter** Device Category Name **Retainer**, **Orthodontics**. **UMDNS CODE:** 13370 Intended Purpose: **This product is intended for use as a lingual retainer wire to maintain tooth position after orthodontic treatment**.

The undersigned hereby declares, on behalf of Permatter LLC, 175 SW 7th St, Ste 1517, Miami, FL 33130, USA, that the above-referenced product, 'Permatter,' meets all requirements of the latest versions of the MDR Regulations (EU) 2017/745 applicable to it.

RELATED DIRECTIVES AND CLASSIFICATION: Medical Devices Regulation (EU) 2017/745 Classification: Class I

Issue Date : 22.01.2024 Validity Date: 21.01.2027 Issue in: Miami,FL-USA Signed on behalf of the Manufacturer

Authorized Signature Pamela DZEMICH Quality Manager

EUROPEAN QUALITY CERTIFICATION

The performance of the product identified above is in conformity with the aforementioned standard. This Declaration of Conformity is issued under the sole responsibility of the manufacturer. Signed for and on behalf of the manufacturer by Pamela Dzemich.