

Ultradent Products GmbH ■ Am Westhover Berg 30 ■ 51149 Cologne

To whom it may concern

Katherine Wagner
Tel +49 1713290813
E-mail:
katherine.wagner@ultradent.com

Endo-Eze IFU

Cologne, 28.05.2026

Please note that under the EU Medical Device Regulation (EU) 2017/745 (MDR), the requirement to provide Instructions for Use (IFU) is based on a risk-based approach.

According to Annex I, Chapter III, Section 23.1(d), IFU may be omitted for Class I and Class IIa devices if they can be used safely and as intended without such instructions.

Based on this regulatory framework, Ultradent Products GmbH (UPE) has determined that an IFU is not required for this device. Consequently, no IFU is included with the product packaging.

Kind Regards,



Katherine Wagner
Regulatory, PRRC
Tel: +49 171 32 90 813