

UE DECLARATION OF CONFORMITY



Manufacturer: Micro-Mega SA – 12 Rue du Tunnel – 25000 BESANCON - FRANCE

SRN Number: FR-MF-000004141

Micro-Mega SA certifies that the products listed below conform to regulation MDR 2017/745 for medical devices, taking into account all applicable european harmonised standards and are CE marked in conformance with the exigencies of this regulation This EU declaration of conformity is issued under the sole responsibility of Micro-Mega SA

Intended Purpose: BASIC UDI ID: ++J015BLRNS48:	The medical devices are used for manual catheterism (n°008 to 015) during a non-surgical endodontic treatment. K-Files 008 and 010 are also used in the exploration, initial penetration, and root canal permeabilization.
References to CS used:	There are no Common Specification available for this type of products in the Official Journal of the European Union.
Conformity assesment procedure:	Annexes II, III and IV of MDR 2017/745
Quality Management System:	EN ISO 13485:2016 certificate 9549 rev. 13 issued by GMED on 2025-07-04, expiry 2028-07-17

Function	Delegated General Manager, Micro-Mega SA	Regulatory Affairs Engineer, Micro-Mega SA
Name	CLAUDE Stephane	KHOUYA Chaima
Place	BESANCON (FRANCE)	BESANCON (FRANCE)
Date of signature	2025-07-28	2025-07-25
Signature		

List of product code:

BASIC UDI-ID	PRODUCT CODE	FAMILY	DESIGNATION	CE Class	CE Rule	Technical File
++J015BLRNS48	60040559	K FILES	GenENDO K-FILES N008 L21 (SEPTODONT)	I	5 dash 1	1
++J015BLRNS48	60040560	K FILES	GenENDO K-FILES N008 L25 (SEPTODONT)	I	5 dash 1	1
++J015BLRNS48	60040561	K FILES	GenENDO K-FILES N008 L31 (SEPTODONT)	I	5 dash 1	1
++J015BLRNS48	60040562	K FILES	GenENDO K-FILES N010 L21 (SEPTODONT)	I	5 dash 1	1
++J015BLRNS48	60040563	K FILES	GenENDO K-FILES N010 L25 (SEPTODONT)	I	5 dash 1	1
++J015BLRNS48	60040564	K FILES	GenENDO K-FILES N010 L31 (SEPTODONT)	I	5 dash 1	1
++J015BLRNS48	60040565	K FILES	GenENDO K-FILES N015 L21 (SEPTODONT)	I	5 dash 1	1
++J015BLRNS48	60040566	K FILES	GenENDO K-FILES N015 L25 (SEPTODONT)	I	5 dash 1	1
++J015BLRNS48	60040567	K FILES	GenENDO K-FILES N015 L31 (SEPTODONT)	I	5 dash 1	1