

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 reponsability of Micro-Mega SA

Intended Purpose: UDI ID: ++J015BLRNS48:	Catheterisation (n°006 to 015) and root canal shaping (all other diameters) during a non-surgical endodontic treatment. K-Files 008 and 010 are also used in the exploration, initial penetration and root canal permeabilisation
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. 10 issued by GMED on 2019-07-19, expiry 2022-07-17

Function	Delegated General Manager Micro-Mega SA
Name	CLAUDE Stephane
Place	BESANCON (FRANCE)
Date of signature	2021-05-20
Signature	

List of product code:

BASIC UDI-ID	PRODUCT CODE	FAMILY	DESIGNATION	CE Class	CE Rule	Technical File
++J015BLRNS48	60029909	HEDSTROEM FILES	P6 PRECISION H-FILES N008 L21	I	5 dash 1	1
++J015BLRNS48	60029910	HEDSTROEM FILES	P6 PRECISION H-FILES N008 L25	I	5 dash 1	1
++J015BLRNS48	60029911	HEDSTROEM FILES	P6 PRECISION H-FILES N008 L31	I	5 dash 1	1
++J015BLRNS48	60029912	HEDSTROEM FILES	P6 PRECISION H-FILES N010 L21	I	5 dash 1	1
++J015BLRNS48	60029913	HEDSTROEM FILES	P6 PRECISION H-FILES N010 L25	I	5 dash 1	1
++J015BLRNS48	60029914	HEDSTROEM FILES	P6 PRECISION H-FILES N010 L31	I	5 dash 1	1
++J015BLRNS48	60029915	HEDSTROEM FILES	P6 PRECISION H-FILES N015 L21	I	5 dash 1	1
++J015BLRNS48	60029916	HEDSTROEM FILES	P6 PRECISION H-FILES N015 L25	I	5 dash 1	1
++J015BLRNS48	60029917	HEDSTROEM FILES	P6 PRECISION H-FILES N015 L31	I	5 dash 1	1
++J015BLRNS48	60029918	HEDSTROEM FILES	P6 PRECISION H-FILES N020 L21	I	5 dash 1	1
++J015BLRNS48	60029919	HEDSTROEM FILES	P6 PRECISION H-FILES N020 L25	I	5 dash 1	1
++J015BLRNS48	60029920	HEDSTROEM FILES	P6 PRECISION H-FILES N020 L31	I	5 dash 1	1
++J015BLRNS48	60029921	HEDSTROEM FILES	P6 PRECISION H-FILES N025 L21	I	5 dash 1	1
++J015BLRNS48	60029922	HEDSTROEM FILES	P6 PRECISION H-FILES N025 L25	I	5 dash 1	1
++J015BLRNS48	60029923	HEDSTROEM FILES	P6 PRECISION H-FILES N025 L31	I	5 dash 1	1
++J015BLRNS48	60029924	HEDSTROEM FILES	P6 PRECISION H-FILES N030 L21	I	5 dash 1	1
++J015BLRNS48	60029925	HEDSTROEM FILES	P6 PRECISION H-FILES N030 L25	I	5 dash 1	1
++J015BLRNS48	60029926	HEDSTROEM FILES	P6 PRECISION H-FILES N030 L31	I	5 dash 1	1
++J015BLRNS48	60029927	HEDSTROEM FILES	P6 PRECISION H-FILES N035 L21	I	5 dash 1	1
++J015BLRNS48	60029928	HEDSTROEM FILES	P6 PRECISION H-FILES N035 L25	I	5 dash 1	1

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BASIC UDI-ID	PRODUCT CODE	FAMILY	DESIGNATION	CE Class	CE Rule	Technical File
++J015BLRNS48	60029929	HEDSTROEM FILES	P6 PRECISION H-FILES N035 L31	I	5 dash 1	1
++J015BLRNS48	60029930	HEDSTROEM FILES	P6 PRECISION H-FILES N040 L21	I	5 dash 1	1
++J015BLRNS48	60029931	HEDSTROEM FILES	P6 PRECISION H-FILES N040 L25	I	5 dash 1	1
++J015BLRNS48	60029932	HEDSTROEM FILES	P6 PRECISION H-FILES N040 L31	I	5 dash 1	1
++J015BLRNS48	60029933	HEDSTROEM FILES	P6 PRECISION H-FILES N045 L21	I	5 dash 1	1
++J015BLRNS48	60029934	HEDSTROEM FILES	P6 PRECISION H-FILES N045 L25	I	5 dash 1	1
++J015BLRNS48	60029935	HEDSTROEM FILES	P6 PRECISION H-FILES N045 L31	I	5 dash 1	1
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++J015BLRNS48	60029937	K FILES	P6 PRECISION K-FILES N008 L25	I	5 dash 1	1
++J015BLRNS48	60029938	K FILES	P6 PRECISION K-FILES N008 L31	I	5 dash 1	1
++J015BLRNS48	60029939	K FILES	P6 PRECISION K-FILES N010 L21	I	5 dash 1	1
++J015BLRNS48	60029940	K FILES	P6 PRECISION K-FILES N010 L25	I	5 dash 1	1
++J015BLRNS48	60029941	K FILES	P6 PRECISION K-FILES N010 L31	I	5 dash 1	1
++J015BLRNS48	60029942	K FILES	P6 PRECISION K-FILES N015 L21	I	5 dash 1	1
++J015BLRNS48	60029943	K FILES	P6 PRECISION K-FILES N015 L25	I	5 dash 1	1
++J015BLRNS48	60029944	K FILES	P6 PRECISION K-FILES N015 L31	I	5 dash 1	1
++J015BLRNS48	60029945	K FILES	P6 PRECISION K-FILES N020 L21	I	5 dash 1	1
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++J015BLRNS48	60029947	K FILES	P6 PRECISION K-FILES N020 L31	I	5 dash 1	1
++J015BLRNS48	60029948	K FILES	P6 PRECISION K-FILES N025 L21	I	5 dash 1	1
++J015BLRNS48	60029949	K FILES	P6 PRECISION K-FILES N025 L25	I	5 dash 1	1
++J015BLRNS48	60029950	K FILES	P6 PRECISION K-FILES N025 L31	I	5 dash 1	1
++J015BLRNS48	60029951	K FILES	P6 PRECISION K-FILES N030 L21	I	5 dash 1	1
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++J015BLRNS48	60029953	K FILES	P6 PRECISION K-FILES N030 L31	I	5 dash 1	1
++J015BLRNS48	60029954	K FILES	P6 PRECISION K-FILES N035 L21	I	5 dash 1	1
++J015BLRNS48	60029955	K FILES	P6 PRECISION K-FILES N035 L25	I	5 dash 1	1
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++J015BLRNS48	60029957	K FILES	P6 PRECISION K-FILES N040 L21	I	5 dash 1	1
++J015BLRNS48	60029958	K FILES	P6 PRECISION K-FILES N040 L25	I	5 dash 1	1
++J015BLRNS48	60029959	K FILES	P6 PRECISION K-FILES N040 L31	I	5 dash 1	1
++J015BLRNS48	60029960	K FILES	P6 PRECISION K-FILES N045 L21	I	5 dash 1	1
++J015BLRNS48	60029961	K FILES	P6 PRECISION K-FILES N045 L25	I	5 dash 1	1
++J015BLRNS48	60029962	K FILES	P6 PRECISION K-FILES N045 L31	I	5 dash 1	1
++J015BLRNS48	60029963	K REAMERS	P6 PRECISION K-REAMERS N008 L21	I	5 dash 1	1
++J015BLRNS48	60029964	K REAMERS	P6 PRECISION K-REAMERS N008 L25	I	5 dash 1	1
++J015BLRNS48	60029965	K REAMERS	P6 PRECISION K-REAMERS N008 L31	I	5 dash 1	1
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++J015BLRNS48	60029967	K REAMERS	P6 PRECISION K-REAMERS N010 L25	I	5 dash 1	1
++J015BLRNS48	60029968	K REAMERS	P6 PRECISION K-REAMERS N010 L31	I	5 dash 1	1
++J015BLRNS48	60029969	K REAMERS	P6 PRECISION K-REAMERS N015 L21	I	5 dash 1	1
++J015BLRNS48	60029970	K REAMERS	P6 PRECISION K-REAMERS N015 L25	I	5 dash 1	1
++J015BLRNS48	60029971	K REAMERS	P6 PRECISION K-REAMERS N015 L31	I	5 dash 1	1
++J015BLRNS48	60029972	K REAMERS	P6 PRECISION K-REAMERS N020 L21	I	5 dash 1	1
++J015BLRNS48	60029973	K REAMERS	P6 PRECISION K-REAMERS N020 L25	I	5 dash 1	1
++J015BLRNS48	60029974	K REAMERS	P6 PRECISION K-REAMERS N020 L31	I	5 dash 1	1
++J015BLRNS48	60029975	K REAMERS	P6 PRECISION K-REAMERS N025 L21	I	5 dash 1	1
++J015BLRNS48	60029976	K REAMERS	P6 PRECISION K-REAMERS N025 L25	I	5 dash 1	1
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++J015BLRNS48	60029978	K REAMERS	P6 PRECISION K-REAMERS N030 L21	I	5 dash 1	1
++J015BLRNS48	60029979	K REAMERS	P6 PRECISION K-REAMERS N030 L25	I	5 dash 1	1
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++J015BLRNS48	60029981	K REAMERS	P6 PRECISION K-REAMERS N035 L21	I	5 dash 1	1
++J015BLRNS48	60029982	K REAMERS	P6 PRECISION K-REAMERS N035 L25	I	5 dash 1	1
++J015BLRNS48	60029983	K REAMERS	P6 PRECISION K-REAMERS N035 L31	I	5 dash 1	1
++J015BLRNS48	60029984	K REAMERS	P6 PRECISION K-REAMERS N040 L21	I	5 dash 1	1
++J015BLRNS48	60029985	K REAMERS	P6 PRECISION K-REAMERS N040 L25	I	5 dash 1	1
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++J015BLRNS48	60029987	K REAMERS	P6 PRECISION K-REAMERS N045 L21	I	5 dash 1	1
++J015BLRNS48	60029988	K REAMERS	P6 PRECISION K-REAMERS N045 L25	I	5 dash 1	1
++J015BLRNS48	60029989	K REAMERS	P6 PRECISION K-REAMERS N045 L31	I	5 dash 1	1