EC Declaration of Conformity

Identification of the Legal Manufacturer:	MEDICEM Technology s.r.o. Karlovarská třída 20 Kamenné Žehrovice, Czech Republic, CZ 273 01

This Declaration of Conformity is issued under the sole responsibility of the Legal Manufacturer.

	Specification:	GTIN:
Unique Device Identifier (UDI):	Dilapan-S 3x55 mm	08595231700284
	Dilapan-S 4x55 mm	08595231700277
	Dilapan-S 4x65 mm	08595231700260
	Dilasoft 3x55 mm	08595231743557
	Dilasoft 4x55 mm	08595231744554
	Dilasoft 4x65 mm	08595231744653

Identification of the device(s) concerned:	Hygroscopic cervical dilators Dilapan-S® Dilasoft 3x55 mm, 4x55 mm, 4x65 mm
Risk Classification:	Class IIa as per Rule 5 in Annex IX

We hereby declare that the above mentioned devices comply with the European Medical Devices Directive 93/42/EEC as modified by 2007/47/EC.

Relevant Harmonized Standards	EN 556-1:2001	EN ISO 11137-2:2015
	EN ISO 15223-1:2016	EN ISO 11607-1:2017
	EN 1041:2008	EN ISO 11607-2:2006
	EN ISO 10993-1:2009	EN ISO 11737-1:2018
	EN ISO 10993-5:2009	EN ISO 11737-2:2009
	EN ISO 10993-10:2013	EN ISO 13485:2016
	EN ISO 11137-1:2015	EN ISO 14971:2012

Name and address of Notified Body:	BSI Group The Netherlands B.V. – NB # 2797 Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands
Applicable CE Certificate(s):	EC Full Quality Assurance System Certificate No. CE 651207, issued by the BSI (NB # 2797), in accordance with Annex II (excluding Section 4) of this Directive.

Date of first CE Marking (using NB # 0086):	28 September 2016
Identification of the person authorized to sign on behalf of Legal Manufacturer:	Name: Jana Šubrtová Signature: Title: QA, QC and Regulatory Director Place of Issue: Kamenné Žehrovice, Czech Republic Date: June 18, 2020