EC Declaration of Conformity

This declaration of conformity is issued under the sole responsibility of SPIDENT Co., Ltd. We herewith declare that the under-mentioned products are in conformity with the general safety and performance requirements and provisions of Regulation (EU) 2017/745 on medical devices. All supporting documentation is retained under the premises of the manufacturer.

Common Name (Product Name) **Temporary crown and bridge resin**

Brand Name **Hexa-Temp**

Model Name **Hexa-Temp A1, Hexa-Temp A2, Hexa-Temp A3, Hexa-Temp B1, Hexa-Temp C2, Hexa-Temp AO3, Hexa-Temp TW, Hexa-Temp Sample A1, Hexa-Temp Sample A2**

EMDN Code **Q0102050101 [TEMPORARY TEETH RESINS]**

Product Code

MDN/MDA Code **MDN1103**

MDS Code **MDS 1007**

MDT Code **MDT2002, MDT2006, MDT2011**

Catalogue Number

Model Name	Reference No.
Hexa-Temp TW	#1204TW
Hexa-Temp A1	#1204A1
Hexa-Temp A2	#1204A2
Hexa-Temp A3	#1204A3
Hexa-Temp B1	#1204B1
Hexa-Temp C2	#1204C2
Hexa-Temp AO3	#1204AO3
Hexa-Temp Sample A1	#1204A1SA
Hexa-Temp Sample A2	#1204A2SA

Basic UDI-DI **880926295HX37**

Classification **Class IIa**
(Regulation (EU) 2017/745, Annex VIII Rule 19)

Manufacturer

- Name **SPIDENT CO., LTD.**

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- SRN **KR-MF-000008691**

EC Declaration of Conformity

European representative	**AR Experts B.V. (tradename: CE Medical)** **Amerlandseweg 7, 3621 ZC, Breukelen, the Netherlands** **TEL. +31 (0)85 007 32 20** **SRN:NL-AR-000000235**
Applied Standard:	**EN ISO 13485:2016/AC:2016+AC:2018, EN ISO 14971:2019, EN 1641:2009, EN SO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-11:2018, EN ISO 7405:2018, EN ISO 10993-10:2013, EN 62366-1:2015, EN ISO 15223-1:2016, EN ISO 20417:2021, ISTA 2A, ISO 10477:2018, ASTM F1980, MEDDEV 2.7/1 [Rev.4]:2016, MEDDEV 2.12/1 [Rev.8]:2013, MEDDEV 2.12/2 [Rev.2]:2012, ISO/TR 24971:2020, MDCG 2020-05, MDCG 2020-06, MDCG 2020-07, MDCG 2020-08**
Notified Body	**DNV Product Assurance AS, Notified Body 2460** **Veritasveien 3, 1363 Høvik, Norway** CE 2460
Conformity Assessment Route	**Annex IX, (Chapter I & III) of Regulation (EU) 2017/745 on Medical Devices**
EC Certificate:	**C587048 NoMA KOR**
EC Certificate Expiry Date :	**March 05, 2028**
Place of Issue	**Incheon, Korea**
Date of Issue	**April 19 2024**

Signature:

Tae Hoon Kim
Person Responsible for Regulatory Compliance
behalf of SPIDENT Co., Ltd.