

EC Declaration of Conformity

We herewith declare that the under-mentioned products are in conformity with the essential requirements and provisions of Council Directive 93/42/EEC as amended by Directive 2007/47/EC. All supporting documentation is retained under the premises of the manufacturer.

Manufacturer's Name: HASS CORP.

Manufacturer's Address : 77-14, Gwahakdanji-ro, Gangneung-si, Gangwon-do, Korea

Product Name: Zirtooth

Model Name: Total 526 types including Zirtooth H S-4019-H
(See attachment for details of type numbers)

Classification : Class IIa (Council Directive 93/42/EEC as amended by Directive 2007/47/EC, Annex IX Rule 8)

Conformity Assessment Route : Annex V, Council Directive 93/42/EEC as amended by Directive 2007/47/EC

GMDN Code: 34755, Dental ceramic

Notified Body : SZUtest Conformity Assessment Incorporated Company
Notified Body Number 2195

EC Certificate No. : 2195-MED-1220502(Valid until 2020-07-21)

Standards applied : EN ISO13485:2012, EN ISO14971:2012, ISO5017:2013,
ISO 6872:2015, ISO 9693:1999, EN ISO10993-1:2009,
EN ISO 10993-3:2014, EN ISO 10993-5:2009,
EN ISO 10993-10:2013, EN ISO 10993-11:2009,
EN ISO 13356:2008, EN ISO15223-1:2012,
EN 62366:2015, EN ISO 7405:2008, EN 1641:2009,
ISO 14155-1:2003, MEDDEV 2.7.1 Rev.4,
MEDDEV 2.12/1 Rev.8, MEDDEV 2.12/2 Rev.2

EC Representative : KTR Europe GmbH
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 2195 **HASS Corporation**
Signature : 
Yongsu, Kim **Yongsu Kim / MD**

Starting date of CE Marking : July.24,2012
Place and date of issue : Gangwon-do / January.02,2019

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Manufacturer's Name: HASS CORP.

Manufacturer's Address: 77-14, Gwahakdanji-ro, Gangneung-si, Gangwon-do, Korea

Product Name: Rosetta BM

Model Name: Total 220 models including Rosetta BM LT C5/W1
(See attachment for details of type numbers)

Classification : Class IIa (Council Directive 93/42/EEC as amended by Directive 2007/47/EC, Annex IX Rule 8)

Conformity Assessment Route : Annex V, Council Directive 93/42/EEC as amended by Directive 2007/47/EC

GMDN Code: 34755, Dental ceramic

Notified Body : SZUtest Conformity Assessment Incorporated Company,
Notified Body Number 2195

EC Certificate No. : 2195-MED-1220502(Valid until 2020-07-21)

Standards applied : EN ISO13485:2012, EN ISO14971:2012, ISO5017:2013,
ISO6872:2015, ISO9693:1999, EN ISO10993-1:2009,
EN ISO10993-3:2014, EN ISO10993-5:2009, EN ISO10993-10:2013,
EN ISO10993-11:2009, EN ISO15223-1:2012, EN1041:2008,
EN62366:2015, EN ISO7405:2008, EN1641:2009,
MEDDEV 2.7.1 Rev.4, MEDDEV 2.12/1 Rev.8, MEDDEV 2.12/2 Rev.2

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Yongsu, Kim / CEO

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Manufacturer's Name: HASS CORP.

Manufacturer's Address : 77-14, Gwahakdanji-ro, Gangneung-si, Gangwon-do, Korea

Product Name: Amber Mill, Amber Press, Amber LiSi-POZ

Model Name: [Milling Type – Amber Mill]

Total 1836 models including Amber Mill LT R7/W1,

[Casting Type – Amber LiSi-POZ, Amber Press]

Total 188 models including Amber Press LT R7/W1

Total 188 models including Amber LiSi-POZ LT R7/W1

(See attachment for details of type numbers)

Classification : Class IIa (Council Directive 93/42/EEC as amended by Directive 2007/47/EC, Annex IX Rule 8)

Conformity Assessment Route : Annex V, Council Directive 93/42/EEC as amended by Directive 2007/47/EC

GMDN Code: 34755, Dental ceramic

Notified Body : SZUtest Conformity Assessment Incorporated Company,
Notified Body Number 2195

EC Certificate No. : 2195-MED-1220502(Valid until 2020-07-21)

Standards applied : EN ISO13485:2012, EN ISO14971:2012, ISO5017:2013,
ISO6872:2015, ISO9693:1999, EN ISO10993-1:2009, EN ISO10993-3:2014,
EN ISO10993-5:2009, EN ISO 10993-10:2013, EN ISO10993-11:2009,
EN ISO15223-1:2012, EN1041:2008, EN 62366:2015, EN ISO7405:2008,
EN1641:2009, MEDDEV 2.7.1 Rev.4, MEDDEV 2.12/1 Rev.8,
MEDDEV 2.12/2 Rev.3

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Signature :

Yongsu, Kim / CEO

Yongsu Kim / MD

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