

EC Declaration of Conformity

We, the

Harvard Dental International GmbH
SRN: DE-MF-000010845

Margaretenstraße 2-4, 15366 Hoppegarten, Germany

with location

Robert-Bosch-Straße 2, 25335 Elmshorn, Germany

hereby declare under our sole responsibility that the medical devices

EMDN-code Q010201, dental impression materials, alginates and others,

Product Name	basic UDI-DI	Classification according Directive 93/42/EEC
Harvard Bite	++EHARHAR016U2	Class I (rule 5)
Harvard TripleBite	++EHARHAR068UM	Class I (rule 5)
Harvard TransMatrix	++EHARHAR018U6	Class I (rule 5)
Harvard LiquiCord	++EHARHAR733V5	Class I (rule 5)
Harvard PremiumSil Light	++EHARHAR712UV	Class I (rule 5)
Harvard PremiumSil Medium	++EHARHAR713UX	Class I (rule 5)
Harvard PremiumSil Mono	++EHARHAR714UZ	Class I (rule 5)
Harvard PremiumSil Mono Maximix	++EHARHAR754VD	Class I (rule 5)
Harvard PremiumSil Heavy	++EHARHAR715V3	Class I (rule 5)
Harvard PremiumSil Heavy MaxiMix	++EHARHAR755VF	Class I (rule 5)
Harvard PremiumSil Putty	++EHARHAR706V2	Class I (rule 5)
Harvard PremiumSil Putty Fast	++EHARHAR706V2	Class I (rule 5)
Harvard PremiumSil Putty Soft	++EHARHAR707V4	Class I (rule 5)
Harvard PremiumSil Putty Soft MaxiMix	++EHARHAR757VK	Class I (rule 5)
Harvard SuperSnap Light	++EHARHAR742V6	Class I (rule 5)
Harvard SuperSnap Medium	++EHARHAR743V8	Class I (rule 5)
Harvard SuperSnap Mono	++EHARHAR744VA	Class I (rule 5)
Harvard SuperSnap Heavy	++EHARHAR745VC	Class I (rule 5)
Harvard SuperSnap Heavy MaxiMix	++EHARHAR755VF	Class I (rule 5)
Harvard SuperSnap Putty	++EHARHAR746VE	Class I (rule 5)
Harvard SuperSnap Putty Soft	++EHARHAR747VG	Class I (rule 5)
Harvard SuperSnap Putty Soft MaxiMix	++EHARHAR757VK	Class I (rule 5)
Harvard TraySive	++EHARHAR026U5	Class I (rule 5)

are in compliance with the requirements of the Directive 93/42/EEC and in accordance with Article 120 of the Regulation (EU) 2017/745, including the amendments made by Regulation (EU) 2023/607.

Conformity Assessment

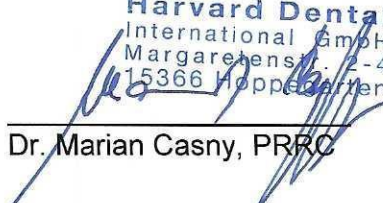
Procedure: According to Annex VII of the Directive 93/42/EEC.

Reference Standards: Applicable standards are part of the Technical Documentation. A list of the concerned standards can be looked up upon request.

Validity: 2025-12-08

Elmshorn, 2024-01-04

Place, date

Harvard Dental
International GmbH
Margaretenstr. 2-4
15366 Hoppegarten

Dr. Marian Casny, PRRC

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EMDN-code Z121101, instruments for dental treatment units

Product Name	basic UDI-DI	Classification according Regulation EU 2017/745
Harvard NeedleTips H17	++EHARHAR7095157MR	Class I (rule 5)
Harvard NeedleTips H18	++EHARHAR7095158MT	Class I (rule 5)
Harvard NeedleTips H18 white	++EHARHAR7083875N5	Class I (rule 5)
Harvard NeedleTips H20	++EHARHAR7091226LP	Class I (rule 5)
Harvard NeedleTips H22	++EHARHAR7095162MJ	Class I (rule 5)
Harvard NeedleTips H25	++EHARHAR7095162ME	Class I (rule 5)
Harvard EndoTips	++EHARHAR7083618ZJ	Class I (rule 5)
Harvard Mini 1:1 S-Brown	++EHARHAR7091050LA	Class I (rule 5)
Harvard Auto 4:1 / 10:1 S-Blue	++EHARHAR7094000LG	Class I (rule 5)
Harvard Microbrush®	++EHARHAR7095156MP	Class I (rule 5)
Harvard Auto 1:1 O-Yellow	++EHARHAR7091300LA	Class I (rule 5)
Harvard Auto-T 1:1 O-Yellow	++EHARHAR7098000MC	Class I (rule 5)
Harvard Auto 1:1 O-Green	++EHARHAR7096000LW	Class I (rule 5)
Harvard Auto-T 1:1 O-Green	++EHARHAR7098010MF	Class I (rule 5)
Harvard Auto 1:1 O-Pink	++EHARHAR7091200L5	Class I (rule 5)
Harvard Auto-T 1:1 O-Pink	++EHARHAR7098020MJ	Class I (rule 5)
Harvard Auto 1:1 / 2:1 light blue	++EHARHAR7091060LD	Class I (rule 5)
Harvard IntraTips, long	++EHARHAR7083620M2	Class I (rule 5)
Harvard IntraTips, yellow	++EHARHAR7083619MH	Class I (rule 5)
Harvard Mini 1:1 O-Brown	++EHARHAR7083610LX	Class I (rule 5)
Harvard Mini 4:1 / 10:1 O-Brown	++EHARHAR7091100KY	Class I (rule 5)
Harvard Mini 4:1 / 10:1 S-Brown	++EHARHAR7093050LQ	Class I (rule 5)

EMDN-code Z121101, instruments for dental treatment units

Product Name	basic UDI-DI	Classification according Regulation EU 2017/745
Harvard Applier OptiCaps®	++EHARHAR7092000L2	Class I (rule 2)
Harvard Applier OptiTips®	++EHARHAR7095200LZ	Class I (rule 2)
Harvard Dispenser Automix 4:1/10:1	++EHARHAR7095000LP	Class I (rule 2)
Harvard Dispenser Automix 1:1	++EHARHAR7095100LU	Class I (rule 2)
Harvard Dispenser Automix 1:1/2:1	++EHARHAR7095600MM	Class I (rule 2)

are in compliance with the requirements of the Regulation (EU) 2017/745 of the European Parliament and the Council.

Conformity Assessment

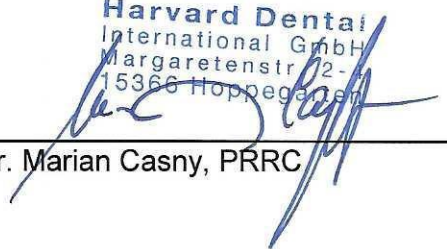
Procedure: According to Annex II and Annex III of the Regulation (EU) 2017/745.

Reference Standards: Applicable standards are part of the Technical Documentation. A list of the concerned standards can be looked up upon request.

Validity: 2025-12-08

Elmshorn, 2024-01-04
Place, date

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EMDN-code Q010101, dental restorative devices,

Product Name	basic UDI-DI	Classification according Regulation EU 2017/745
Harvard MultiChrome	++EHARHAR160UA	Class IIa (rule 8/19)
Harvard MultiChrome / Harvard Block'n Mask	++EHARHAR160UA	Class IIa (rule 8/19)
Harvard MultiChrome Flow	++EHARHAR162UE	Class IIa (rule 8/19)
Harvard Block'n Mask	++EHARHAR170UD	Class IIa (rule 8/19)
Harvard Block'n Mask Flow	++EHARHAR172UH	Class IIa (rule 8/19)
Harvard UltraFill	++EHARHAR150U7	Class IIa (rule 8/19)
Harvard UltraFill OptiTips	++EHARHAR150U7	Class IIa (rule 8/19)
Harvard UltraFill Flow	++EHARHAR155UH	Class IIa (rule 8/19)
Harvard PremiumFill	++EHARHAR182UL	Class IIa (rule 8/19)
Harvard PremiumFill+	++EHARHAR182UL	Class IIa (rule 8/19)
Harvard Premium Flow	++EHARHAR184UQ	Class IIa (rule 8/19)
Harvard Premium Flow+	++EHARHAR184UQ	Class IIa (rule 8/19)
Harvard IonoSphere Bulk Flow	++EHARHAR147UJ	Class IIa (rule 8/19)
Harvard Restore	++EHARHAR101TS	Class IIa (rule 8/19)
Harvard Restore Flow	++EHARHAR104TY	Class IIa (rule 8/19)
Harvard Restore System Kit	++EHARHAR101TS	Class IIa (rule 8/19)
Harvard Restore System Kit Plus	++EHARHAR101TS	Class IIa (rule 8/19)
Harvard Restore System Kit Self-Bond	++EHARHAR101TS	Class IIa (rule 8/19)
Harvard Restore System Kit SE Mono	++EHARHAR101TS	Class IIa (rule 8/19)
Harvard InterLock ONE	++EHARHAR205U7	Class IIa (rule 8)
Harvard InterLock ONE Single Dose	++EHARHAR205U7	Class IIa (rule 8)
Harvard InterLock ONE Self Cure Activator	++EHARHAR224UB	Class IIa (rule 8)
Harvard InterLock	++EHARHAR207UB	Class IIa (rule 8)
Harvard Bond SE Mono	++EHARHAR206U9	Class IIa (rule 8)
Harvard Self-Bond	++EHARHAR202TZ	Class IIa (rule 8/19)
Harvard Bond TE Mono	++EHARHAR212U4	Class IIa (rule 8)
Harvard Etch	++EHARHAR401U9	Class IIa (rule 6/19)
Harvard IonoLine	++EHARHAR231U8	Class IIa (rule 8/19)
Harvard VeneerCem	++EHARHAR173UK	Class IIa (rule 8/19)

EMDN-code Q010101, dental restorative devices,

Product Name	basic UDI-DI	Classification according Regulation EU 2017/745
Harvard Core	++EHARHAR127UC	Class IIa (rule 8/19)
Harvard IonoGlas Core	++EHARHAR138UH	Class IIa (rule 8/19)
Harvard ZirconCore	++EHARHAR127UC	Class IIa (rule 8/19)
Harvard Bond SE Dual	++EHARHAR227UH	Class IIa (rule 8/19)
Harvard LuteCem SE	++EHARHAR464UZ	Class IIa (rule 8/19)

EMDN-code Q010199, devices for conservative dentistry and endodontics - others,

Product Name	basic UDI-DI	Classification according Regulation EU 2017/745
Harvard BioCal CAP	++EHARHAR234UE	Class IIa (rule 8/19)
Harvard BioCal Line	++EHARHAR233UC	Class IIa (rule 8/19)
Harvard BioCal RootSeal	++EHARHAR130TZ	Class IIa (rule 8/19)
Harvard MTA Universal	++EHARHAR450UN	Class IIa (rule 8/19)
Harvard MTA-Repair	++EHARHAR451UQ	Class IIa (rule 8/19)
Harvard MTA-Retro	++EHARHAR452US	Class IIa (rule 8/19)
Harvard MTA-CAP	++EHARHAR453UU	Class IIa (rule 8/19)
Harvard MTA-PT	++EHARHAR453UU	Class IIa (rule 8/19)
Harvard MTA-Ortho	++EHARHAR454UW	Class IIa (rule 8/19)
Harvard MTA-Ortho OptiCaps & EndoDirect	++EHARHAR454UW	Class IIa (rule 8/19)
Harvard MTA RootSeal	++EHARHAR455UY	Class IIa (rule 8/19)
Harvard RootTemp	++EHARHAR540UQ	Class IIa (rule 8/19)
Harvard CalciumHydroxide	++EHARHAR540UQ	Class IIa (rule 8/19)
Harvard CalciumHydroxide LC	++EHARHAR232UA	Class IIa (rule 8/19)
Harvard Glide&Clean	++EHARHAR405UH	Class IIa (rule 6/19)

EMDN-code Q010205, resins and dental crowns,

Product Name	basic UDI-DI	Classification according Regulation EU 2017/745
Harvard TEMP C&B	++EHARHAR316UH	Class IIa (rule 8/19)
Harvard TEMP C&B Pro	++EHARHAR317UK	Class IIa (rule 8/19)
Harvard TEMP C&B Ultra	++EHARHAR314UD	Class IIa (rule 8/19)
Harvard TEMP Glaze LC	++EHARHAR305UC	Class IIa (rule 5/19)
Harvard TEMP Cem Esthetic	++EHARHAR321UA	Class IIa (rule 7/19)
Harvard TEMP Cem	++EHARHAR322UC	Class IIa (rule 7/19)
Harvard TEMP Cem EasyDose	++EHARHAR322UC	Class IIa (rule 7/19)
Harvard Implant	++EHARHAR867VT	Class IIa (rule 7/19)

EMDN-code Q010101, dental restorative devices,

Product Name	basic UDI-DI	Classification according Regulation EU 2017/745
Harvard Cement	++EHARHAR551UV	Class IIa (rule 8/19)
Harvard Cement OptiCaps	++EHARHAR551UV	Class IIa (rule 8/19)
Harvard Polycarboxylat Cement	++EHARHAR552UX	Class IIa (rule 8/19)
Harvard IonoGlas Fill Extra	++EHARHAR561UY	Class IIa (rule 8/19)
Harvard IonoGlas Fill Extra OptiCaps	++EHARHAR561UY	Class IIa (rule 8/19)
Harvard IonoGlas Fill	++EHARHAR511UH	Class IIa (rule 8/19)
Harvard IonoResin Fill LC	++EHARHAR501UE	Class IIa (rule 8/19)
Harvard IonoResin Fill Extra	++EHARHAR521UL	Class IIa (rule 8/19)
Harvard IonoResin Fill Extra OptiCaps	++EHARHAR521UL	Class IIa (rule 8/19)
Harvard IonoGlas Cem Extra	++EHARHAR563V4	Class IIa (rule 8/19)
Harvard IonoGlas Cem Extra OptiCaps	++EHARHAR563V4	Class IIa (rule 8/19)
Harvard IonoGlas Cem	++EHARHAR513UM	Class IIa (rule 8/19)
Harvard IonoResin Cem LC	++EHARHAR503UJ	Class IIa (rule 8/19)
Harvard IonoResin Cem Extra	++EHARHAR523UQ	Class IIa (rule 8/19)
Harvard IonoResin Cem Extra OptiCaps	++EHARHAR523UQ	Class IIa (rule 8/19)
Harvard IonoCoat LC	++EHARHAR598VP	Class IIa (rule 5/19)
Harvard Ionoconditioner	++EHARHAR520UJ	Class IIa (rule 5/19)
Harvard IonoResin Prime LC	++EHARHAR580V4	Class IIa (rule 8/19)

are in compliance with the requirements of the Directive 93/42/EEC and in accordance with Article 120 of the Regulation (EU) 2017/745, including the amendments made by Regulation (EU) 2023/607.

Conformity Assessment

Procedure: According to Annex II excluding section 4 of the Directive 93/42/EEC.

Notified Body:

DNV MedCert GmbH, Pilatuspool 2, 20355 Hamburg,
Identification-Number: 0482.

Reference Standards:

Applicable standards are part of the Technical Documentation. A list of the concerned standards can be looked up upon request.

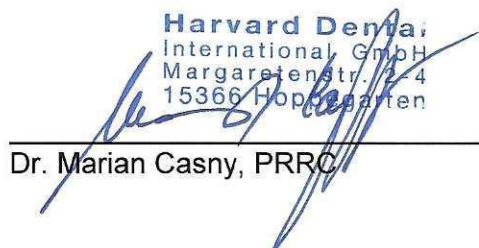
Certificate No.: 7046GB448231214

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