

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

Group 1: Composites and Bondings

Product Name	Classification
Harvard MultiChrome	Class IIa (rule 8)
Harvard MultiChrome / Harvard Block'n Mask	Class IIa (rule 8)
Harvard MultiChrome Flow	Class IIa (rule 8)
Harvard Block'n Mask	Class IIa (rule 8)
Harvard Block'n Mask Flow	Class IIa (rule 8)
Harvard UltraFill	Class IIa (rule 8)
Harvard UltraFill OptiTips	Class IIa (rule 8)
Harvard UltraFill Flow	Class IIa (rule 8)
Harvard UltraFill Flow ComforTip F	Class IIa (rule 8)
Harvard PremiumFill	Class IIa (rule 8)
Harvard PremiumFill+ OptiTips	Class IIa (rule 8)
Harvard Premium Flow	Class IIa (rule 8)
Harvard Premium Flow+	Class IIa (rule 8)
Harvard IonoSphere Bulk Flow	Class IIa (rule 8)
Harvard Restore	Class IIa (rule 8)
Harvard Restore XN	Class IIa (rule 8)
Harvard Restore XN System Kit Plus	Class IIa (rule 8)
Harvard Restore Flow	Class IIa (rule 8)
Harvard Restore XN Flow	Class IIa (rule 8)
Harvard Restore System Kit	Class IIa (rule 8)
Harvard Restore System Kit Plus	Class IIa (rule 8)
Harvard Restore System Kit Self-Bond	Class IIa (rule 8)
Harvard Restore System Kit SE Mono	Class IIa (rule 8)

Harvard InterLock ONE	Class IIa (rule 8)
Harvard InterLock ONE Single Dose	Class IIa (rule 8)
Harvard InterLock ONE Self Cure Activator	Class IIa (rule 8)
Harvard InterLock	Class IIa (rule 8)
Harvard Bond SE Mono	Class IIa (rule 8)
Harvard Self-Bond	Class IIa (rule 8)
Harvard Bond TE Mono	Class IIa (rule 8)
Harvard Etch	Class IIa (rule 8)
Harvard IonoLine	Class IIa (rule 8)

Group 2: Post Cementing and Core Build-Up

Product Name	Classification
Harvard Core	Class IIa (rule 8)
Harvard IonoGlas Core	Class IIa (rule 8)
Harvard ZirconCore	Class IIa (rule 8)
Harvard Bond SE Dual	Class IIa (rule 8)
Harvard LuteCem SE	Class IIa (rule 8)

Group 3: Endodontics

Product Name	Classification
Harvard BioCal CAP	Class IIa (rule 8)
Harvard BioCal Line	Class IIa (rule 8)
Harvard BioCal RootSeal	Class IIa (rule 8)
Harvard MTA Universal	Class IIa (rule 8)
Harvard MTA-Repair	Class IIa (rule 8)
Harvard MTA-Retro	Class IIa (rule 8)
Harvard MTA-CAP	Class IIa (rule 8)
Harvard MTA-Ortho	Class IIa (rule 8)
Harvard MTA-Ortho OptiCaps & EndoDirect	Class IIa (rule 8)
Harvard MTA RootSeal	Class IIa (rule 8)
Harvard RootTemp	Class IIa (rule 8)
Harvard CalciumHydroxide	Class IIa (rule 8)
Harvard CalciumHydroxide LC	Class IIa (rule 8)
Harvard Glide&Clean	Class IIa (rule 8)

Group 4: Temporary Materials

Product Name	Classification
Harvard TEMP C&B	Class IIa (rule 7)
Harvard TEMP C&B Pro	Class IIa (rule 7)
Harvard TEMP Glaze LC	Class IIa (rule 7)
Harvard TEMP Cem Esthetic	Class IIa (rule 7)
Harvard TEMP Cem	Class IIa (rule 7)
Harvard TEMP Cem EasyDose	Class IIa (rule 7)
Harvard Implant	Class IIa (rule 7)

Group 5: Cements

Product Name	Classification
Harvard Cement	Class IIa (rule 8)
Harvard Cement OptiCaps	Class IIa (rule 8)
Harvard Polycarboxylat Cement	Class IIa (rule 8)
Harvard IonoGlas Fill Extra	Class IIa (rule 8)
Harvard IonoGlas Fill Extra OptiCaps	Class IIa (rule 8)
Harvard IonoGlas Fill	Class IIa (rule 8)
Harvard IonoResin Fill LC	Class IIa (rule 8)
Harvard IonoResin Fill	Class IIa (rule 8)
Harvard IonoResin Fill Extra	Class IIa (rule 8)
Harvard IonoResin Fill Extra OptiCaps	Class IIa (rule 8)
Harvard IonoGlas Cem Extra	Class IIa (rule 8)
Harvard IonoGlas Cem Extra OptiCaps	Class IIa (rule 8)
Harvard IonoGlas Cem	Class IIa (rule 8)
Harvard IonoResin Cem LC	Class IIa (rule 8)
Harvard IonoResin Cem	Class IIa (rule 8)
Harvard IonoResin Cem Extra	Class IIa (rule 8)
Harvard IonoResin Cem Extra OptiCaps	Class IIa (rule 8)
Harvard Ionocoat LC	Class IIa (rule 8)
Harvard Ionoconditioner	Class IIa (rule 8)
Harvard IonoResin Prime LC	Class IIa (rule 8)

are in compliance with the requirements of the *Directive 93/42/EEC*.

Conformity Assessment

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

Notified Body: MedCert Zertifizierungs- und Prüfungsgesellschaft für die Medizin 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.: 7046GB410200609

Validity: 2023-12-09

Elmshorn, 2021-08-23
Place, date



Dr. Marian Casny, Authorised Person
for Regulatory Compliance