



KONFORMITÄTSERKLÄRUNG DICHIARAZIONE DI CONFORMITÀ DECLARATION OF CONFORMITY DÉCLARATION DE CONFORMITÉ

Hersteller: Bionah srl
Produttore: Via J.G. Mahl 40
Manufacturer: I – 39031 Brunico
Fabricant: Tel. +39 0474 370 350 / Fax.+39 0474 370 351
E-Mail: info@bionah.com / www.bionah.com

Produkt und Zubehör:	BionZ Crystal	BionPV PM
Prodotto e accessori:	BionZ Diamond	BionPV PM+ Layer
Product and accessories:	BionZ Brilliant	
Produit et accessoires:	BionZ Brilliant Layer	BionMet CC
	BionZ Glass	BionMet T2
	BionZ Glass Layer	BionMet T4
	BionZ Coral	BionMet T5
	BionZ Coral Layer	
	BionZ Glacier	
	BionZ Glacier Layer	

Erklärung: In eigener Verantwortung erklären wir, dass die oben angeführten Medizinprodukte der Klasse IIa laut Anhang IX, Regel 8 der Richtlinie 93/42/EWG und 2007/47/EWG angehören und allen Anforderungen der Medizinprodukte-Richtlinien 93/42/EWG und 2007/47/EWG entsprechen. Konformitätsbewertungsverfahren gemäß Anhang II (vollständiges Qualitätssicherungssystem) ohne Punkt 4.
Dichiarazione:
Declaration:
Déclaration:

Dichiaro sotto nostra responsabilità, che i dispositivi sopra indicati sono da classificare IIa secondo l'allegato IX, regola 8 della direttiva 93/42/CEE e 2007/47/CEE e soddisfano tutti requisiti della direttiva 93/42/CEE e 2007/47/CEE. La valutazione della conformità è stata eseguita secondo l'allegato II (sistema completo di garanzia di qualità) senza punto 4.

Herewith we declare under our responsibility that the medical devices listed above are to be classified IIa according to annex IX, rule 8 of direct 93/42/EEC and 2007/47/EEC and meets all the requirements of the directive 93/42/EEC and 2007/47/EEC. Conformity assessment procedure according to annex II (Full quality assurance system) without point 4.

Nous déclarons sous notre propre responsabilité que les dispositifs médicaux énumérés ci-dessus de la classe IIa, règle 8 conformément à l'annexe IX de 93/42/CEE et 2007/47/CEE et directe répondent à toutes les exigences de la directive 93/42/CEE, 2007/47/CEE. Procédure d'évaluation de la conformité conformément à l'annexe II (Système complet d'assurance de la qualité) sans point 4.

Benannte Stelle: TÜV Rheinland Italia S.r.l.
Organismo notificato: Via Mattei, 3
Notified Body: I-Pogliano Milanese
Organisme notifié: T +39 02 939 6871
F +39 02 939 68723



Gültigkeit: Diese Konformitätserklärung ist bis zum 25.05.2025 gültig.
Validità: Questa dichiarazione di conformità è valida fino al 25.05.2025.
Validity: This declaration of conformity is valid until 25.05.2025.
Validité: Cette déclaration de conformité est valable jusqu'au 25.05.2025.

Ort und Datum: Brunico, 03.05.2024
Luogo e data:
Place and date:
Date et lieu:

Direktor - Direttore: Name - Nome – Name – Nom: Pfeifhofer Paul
Director - Directeur: Unterschrift – Firma – Signature – Signature:



**ANHANG KONFORMITÄTSERKLÄRUNG
 APPENDICE DICHIARAZIONE DI CONFORMITÀ
 APPENDIX DECLARATION OF CONFORMITY
 ANNEXE DÉCLARATION DE CONFORMITÉ**

**Produkt:
 Prodotto:
 Product:
 Produit:**

**BionZ Crystal
 BionZ Diamond
 BionZ Brilliant
 BionZ Brilliant Layer
 BionZ Glass
 BionZ Glass Layer
 BionZ Coral
 BionZ Coral Layer
 BionZ Glacier
 BionZ Glacier Layer**

**BionPV PM
 BionPV PM+ Layer
 BionMET CC
 BionMET T2
 BionMET T4
 BionMET T5**

**Artikelnummer:
 Codici d'articolo:
 Item no.:
 Numéro d'article:**

BionZ Crystal
 BZC0010S; BZC0010SC; BZC0020S; BZC0020SC; BZC0030S; BZC0030SC; BZC0040S; BZC0040SC; BZC0050S; BZC0050SC; BZC0060S; BZC0060SC; BZC0070S; BZC0070SC; BZC0080S; BZC0080SC; BZC0090S; BZC0090SC; BZC0100S; BZC0100SC; BZC0110S; BZC0110SC; BZC0110K; BZC0110KC; BZC0110M; BZC0110MC; BZC0120S; BZC0120SC; BZC0120K; BZC0120KC; BZC0120M; BZC0120MC; BZC0130S; BZC0130SC; BZC0130K; BZC0130KC; BZC0130M; BZC0130MC; BZC0140K; BZC0140KC; BZC0140M; BZC0140MC; BZC0150K; BZC0150KC; BZC0160K; BZC0160KC; BZC0180M; BZC0181M; BZC0190M; BZC0191M; BZC0200M; BZC0201M; BZC0210M; BZC0211M; BZC0220M; BZC0221M; BZC0230M; BZC0231M; BZC0240W; BZC0241W; BZC0250W; BZC0251W; BZC0260W; BZC0261W; BZC0270W; BZC0271W; BZC0280W; BZC0281W; BZC0290W; BZC0291W; BZC0300W; BZC0301W; BZC0420W; BZC0421W; BZC0430W; BZC0431W; BZC0310M; BZC0310MC; BZC0320M; BZC0320MC; BZC0330M; BZC0330MC; BZC0340M; BZC0340MC; BZC0500Z; BZC0500ZC; BZC0510Z; BZC0510ZC; BZC0520Z; BZC0520ZC; BZC0530Z; BZC0530ZC; BZC0540Z; BZC0540ZC; BZC0550Z; BZC0550ZC; BZC0560Z; BZC0560ZC; BZC0570Z; BZC0590Z; BZC0730Z; BZC0730ZC; BZC0760Z; BZC0760ZC; BZC0830Z; BZC0830ZC; BZC0860Z; BZC0860ZC; BZC0930Z; BZC0930ZC; BZC0960Z; BZC0960ZC; BZC1030Z; BZC1030ZC; BZC1060Z; BZC1060ZC; BZC1130Z; BZC1130ZC; BZC1160Z; BZC1160ZC; BZC1230Z; BZC1230ZC; BZC1260Z; BZC1260ZC; BZC1330Z; BZC1330ZC; BZC1360Z; BZC1360ZC; BZC1410A; BZC1410AC; BZC1430A; BZC1430AC; BZC1450A; BZC1450AC; BZC0010S-N; BZC0010SC-N; BZC0020S-N; BZC0020SC-N; BZC0030S-N; BZC0030SC-N; BZC0040S-N; BZC0040SC-N; BZC0050S-N; BZC0050SC-N; BZC0060S-N; BZC0060SC-N; BZC0070S-N; BZC0070SC-N; BZC0080S-N; BZC0080SC-N; BZC0090S-N; BZC0090SC-N; BZC0100S-N; BZC0100SC-N; BZC0110S-N; BZC0110SC-N; BZC0110K-N; BZC0110KC-N; BZC0110M-N; BZC0110MC-N; BZC0120S-N; BZC0120SC-N; BZC0120K-N; BZC0120KC-N; BZC0120M-N; BZC0120MC-N; BZC0130S-N; BZC0130SC-N; BZC0130K-N; BZC0130KC-N; BZC0130M-N; BZC0130MC-N; BZC0140K-N; BZC0140KC-N; BZC0140M-N; BZC0140MC-N; BZC0150K-N; BZC0150KC-N; BZC0160K-N; BZC0160KC-N; BZC0180M-N; BZC0181M-N; BZC0190M-N; BZC0191M-N; BZC0200M-N; BZC0201M-N; BZC0210M-N; BZC0211M-N; BZC0220M-N; BZC0221M-N; BZC0230M-N; BZC0231M-N; BZC0240W-N; BZC0241W-N; BZC0250W-N; BZC0251W-N; BZC0260W-N; BZC0261W-N; BZC0270W-N; BZC0271W-N; BZC0280W-N; BZC0281W-N; BZC0290W-N; BZC0291W-N; BZC0300W-N; BZC0301W-N; BZC0420W-N; BZC0421W-N; BZC0430W-N; BZC0431W-N; BZC0310M-N; BZC0310MC-N; BZC0320M-N; BZC0320MC-N; BZC0330M-N; BZC0330MC-N; BZC0340M-N; BZC0340MC-N; BZC0500Z-N; BZC0500ZC-N; BZC0510Z-N; BZC0510ZC-N; BZC0520Z-N; BZC0520ZC-N; BZC0530Z-N; BZC0530ZC-N; BZC0540Z-N; BZC0540ZC-N; BZC0550Z-N; BZC0550ZC-N; BZC0560Z-N; BZC0560ZC-N; BZC0570Z-N; BZC0590Z-N; BZC0730Z-N; BZC0730ZC-N; BZC0760Z-N; BZC0760ZC-N; BZC0830Z-N; BZC0830ZC-N; BZC0860Z-N; BZC0860ZC-N; BZC0930Z-N; BZC0930ZC-N; BZC0960Z-N; BZC0960ZC-N; BZC1030Z-N; BZC1030ZC-N; BZC1060Z-N; BZC1060ZC-N; BZC1130Z-N; BZC1130ZC-N; BZC1160Z-N; BZC1160ZC-N; BZC1230Z-N; BZC1230ZC-N; BZC1260Z-N; BZC1260ZC-N; BZC1330Z-N; BZC1330ZC-N; BZC1360Z-N; BZC1360ZC-N; BZC1410A-N; BZC1410AC-N; BZC1430A-N; BZC1430AC-N; BZC1450A-N; BZC1450AC-N;

BionZ Diamond
 BZD0010S; BZD0010SC; BZD0020S; BZD0020SC; BZD0030S; BZD0030SC; BZD0040S; BZD0040SC; BZD0050S; BZD0050SC; BZD0060S; BZD0060SC; BZD0070S; BZD0070SC; BZD0080S; BZD0080SC; BZD0090S; BZD0090SC; BZD0100S; BZD0100SC; BZD0110S; BZD0110SC; BZD0110K; BZD0110KC; BZD0110M; BZD0110MC; BZD0120S; BZD0120SC; BZD0120K; BZD0120KC; BZD0120M; BZD0120MC; BZD0130S; BZD0130SC; BZD0130K; BZD0130KC; BZD0130M; BZD0130MC; BZD0140K; BZD0140KC; BZD0140M; BZD0140MC; BZD0150K; BZD0150KC; BZD0160K; BZD0160KC; BZD0180M; BZD0181M; BZD0190M; BZD0191M; BZD0200M; BZD0201M; BZD0210M; BZD0211M; BZD0220M; BZD0221M; BZD0230M; BZD0231M; BZD0240W; BZD0241W; BZD0250W; BZD0251W; BZD0260W; BZD0261W; BZD0270W; BZD0271W; BZD0280W; BZD0281W; BZD0290W; BZD0291W; BZD0300W; BZD0301W; BZD0420W; BZD0421W; BZD0430W; BZD0431W; BZD0310M; BZD0310MC; BZD0320M; BZD0320MC; BZD0330M; BZD0330MC; BZD0340M; BZD0340MC; BZD0500Z; BZD0500ZC; BZD0510Z; BZD0510ZC; BZD0520Z; BZD0520ZC; BZD0530Z; BZD0530ZC; BZD0540Z; BZD0540ZC; BZD0550Z; BZD0550ZC; BZD0560Z; BZD0560ZC; BZD0570Z; BZD0590Z; BZD0730Z; BZD0730ZC; BZD0760Z; BZD0760ZC; BZD0830Z; BZD0830ZC; BZD0860Z; BZD0860ZC; BZD0930Z; BZD0930ZC; BZD0960Z; BZD0960ZC; BZD1030Z; BZD1030ZC; BZD1060Z; BZD1060ZC; BZD1130Z; BZD1130ZC; BZD1160Z; BZD1160ZC; BZD1230Z; BZD1230ZC; BZD1260Z; BZD1260ZC; BZD1330Z; BZD1330ZC; BZD1360Z; BZD1360ZC; BZD1410A; BZD1410AC; BZD1430A; BZD1430AC; BZD1450A; BZD1450AC; BZD0010S-N; BZD0010SC-N; BZD0020S-N; BZD0020SC-N; BZD0030S-N; BZD0030SC-N; BZD0040S-N; BZD0040SC-N; BZD0050S-N; BZD0050SC-N; BZD0060S-N; BZD0060SC-N; BZD0070S-N; BZD0070SC-N; BZD0080S-N; BZD0080SC-N; BZD0090S-N; BZD0090SC-N; BZD0100S-N; BZD0100SC-N; BZD0110S-N; BZD0110SC-N; BZD0110K-N; BZD0110KC-N; BZD0110M-N; BZD0110MC-N; BZD0120S-N; BZD0120SC-N; BZD0120K-N; BZD0120KC-N; BZD0120M-N; BZD0120MC-N; BZD0130S-N; BZD0130SC-N; BZD0130K-N; BZD0130KC-N; BZD0130M-N; BZD0130MC-N; BZD0140K-N; BZD0140KC-N; BZD0140M-N; BZD0140MC-N; BZD0150K-N; BZD0150KC-N; BZD0160K-N; BZD0160KC-N; BZD0180M-N; BZD0181M-N; BZD0190M-N; BZD0191M-N; BZD0200M-N; BZD0201M-N; BZD0210M-N; BZD0211M-N; BZD0220M-N; BZD0221M-N; BZD0230M-N; BZD0231M-N; BZD0240W-N; BZD0241W-N; BZD0250W-N; BZD0251W-N; BZD0260W-N; BZD0261W-N; BZD0270W-N; BZD0271W-N; BZD0280W-N; BZD0281W-N; BZD0290W-N; BZD0291W-N; BZD0300W-N; BZD0301W-N; BZD0420W-N; BZD0421W-N; BZD0430W-N; BZD0431W-N; BZD0310M-N; BZD0310MC-N; BZD0320M-N; BZD0320MC-N; BZD0330M-N; BZD0330MC-N; BZD0340M-N; BZD0340MC-N; BZD0500Z-N; BZD0500ZC-N; BZD0510Z-N; BZD0510ZC-N; BZD0520Z-N; BZD0520ZC-N; BZD0530Z-N; BZD0530ZC-N; BZD0540Z-N; BZD0540ZC-N; BZD0550Z-N; BZD0550ZC-N; BZD0560Z-N; BZD0560ZC-N; BZD0570Z-N; BZD0590Z-N; BZD0730Z-N; BZD0730ZC-N; BZD0760Z-N; BZD0760ZC-N; BZD0830Z-N; BZD0830ZC-N; BZD0860Z-N; BZD0860ZC-N; BZD0930Z-N; BZD0930ZC-N; BZD0960Z-N; BZD0960ZC-N; BZD1030Z-N; BZD1030ZC-N; BZD1060Z-N; BZD1060ZC-N; BZD1130Z-N; BZD1130ZC-N; BZD1160Z-N; BZD1160ZC-N; BZD1230Z-N; BZD1230ZC-N; BZD1260Z-N; BZD1260ZC-N; BZD1330Z-N; BZD1330ZC-N; BZD1360Z-N; BZD1360ZC-N; BZD1410A-N; BZD1410AC-N; BZD1430A-N; BZD1430AC-N; BZD1450A-N; BZD1450AC-N;

BionZ Glass
 BZG0010S; BZG0010SC; BZG0020S; BZG0020SC; BZG0030S; BZG0030SC; BZG0040S; BZG0040SC; BZG0050S; BZG0050SC; BZG0060S; BZG0060SC; BZG0070S; BZG0070SC; BZG0080S; BZG0080SC; BZG0090S; BZG0090SC; BZG0100S; BZG0100SC; BZG0110K; BZG0110KC; BZG0110M; BZG0110MC; BZG0120K; BZG0120KC; BZG0120M; BZG0120MC; BZG0130K; BZG0130KC; BZG0130M; BZG0130MC; BZG0140K; BZG0140KC; BZG0140M; BZG0140MC; BZG0150K; BZG0150KC; BZG0160K; BZG0160KC; BZG0180M; BZG0181M; BZG0190M; BZG0191M; BZG0200M; BZG0201M; BZG0210M; BZG0211M; BZG0220M; BZG0221M; BZG0230M; BZG0231M; BZG0240W; BZG0241W; BZG0250W; BZG0251W; BZG0260W; BZG0261W; BZG0270W; BZG0271W; BZG0280W; BZG0281W; BZG0290W; BZG0291W; BZG0300W; BZG0301W; BZG0420W; BZG0421W; BZG0430W; BZG0431W; BZG0310M; BZG0310MC; BZG0320M; BZG0320MC; BZG0330M; BZG0330MC; BZG0340M; BZG0340MC; BZG0500Z; BZG0500ZC; BZG0510Z; BZG0510ZC; BZG0520Z; BZG0520ZC; BZG0530Z; BZG0530ZC; BZG0540Z; BZG0540ZC; BZG0550Z; BZG0550ZC; BZG0560Z; BZG0560ZC; BZG0570Z; BZG0590Z; BZG0730Z; BZG0730ZC; BZG0760Z; BZG0760ZC; BZG0830Z; BZG0830ZC; BZG0860Z; BZG0860ZC; BZG0930Z; BZG0930ZC; BZG0960Z; BZG0960ZC; BZG1030Z; BZG1030ZC; BZG1060Z; BZG1060ZC; BZG1130Z; BZG1130ZC; BZG1160Z; BZG1160ZC; BZG1230Z; BZG1230ZC; BZG1260Z; BZG1260ZC; BZG1330Z; BZG1330ZC; BZG1360Z; BZG1360ZC; BZG1410A; BZG1410AC; BZG1430A; BZG1430AC; BZG1450A; BZG1450AC;

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BPM0116M-N; BPM0120M-N; BPM0125M-N; BPM0130M-N; BPM0216M-N; BPM0220M-N; BPM0225M-N; BPM0230M-N; BPM0316M-N; BPM0320M-N; BPM0325M-N; BPM0330M-N; BPM0716M-N; BPM0720M-N; BPM0725M-N; BPM0730M-N; BPM0916M-N; BPM0920M-N; BPM0925M-N; BPM0930M-N; BPM1016M-N; BPM1020M-N; BPM1025M-N; BPM1030M-N; BPM3116W-N; BPM3120W-N; BPM3125W-N; BPM3130W-N; BPM3216W-N; BPM3220W-N; BPM3225W-N; BPM3230W-N; BPM3316W-N; BPM3320W-N; BPM3325W-N; BPM3330W-N; BPM3716W-N; BPM3720W-N; BPM3725W-N; BPM3730W-N; BPM3916W-N; BPM3920W-N; BPM3925W-N; BPM3930W-N; BPM4016W-N; BPM4020W-N; BPM4025W-N; BPM4030W-N; BPM7116Z-N; BPM7120Z-N; BPM7125Z-N; BPM7130Z-N; BPM7216Z-N; BPM7220Z-N; BPM7225Z-N; BPM7230Z-N; BPM7316Z-N; BPM7320Z-N; BPM7325Z-N; BPM7330Z-N; BPM7716Z-N; BPM7720Z-N; BPM7725Z-N; BPM7730Z-N; BPM7916Z-N; BPM7920Z-N; BPM7925Z-N; BPM7930Z-N; BPM8016Z-N; BPM8020Z-N; BPM8025Z-N; BPM8030Z-N;

BionPV PM+ Layer

BPMPLO116M; BPMPLO120M; BPMPLO125M; BPMPLO130M; BPMPLO216M; BPMPLO220M; BPMPLO225M; BPMPLO230M; BPMPLO316M; BPMPLO320M; BPMPLO325M; BPMPLO330M; BPMPLO316W; BPMPLO3120W; BPMPLO3125W; BPMPLO3130W; BPMPLO3216W; BPMPLO3220W; BPMPLO3225W; BPMPLO3230W; BPMPLO3316W; BPMPLO3320W; BPMPLO3325W; BPMPLO3330W; BPMPLO7116Z; BPMPLO7120Z; BPMPLO7125Z; BPMPLO7130Z; BPMPLO7216Z; BPMPLO7220Z; BPMPLO7225Z; BPMPLO7230Z; BPMPLO7316Z; BPMPLO7320Z; BPMPLO7325Z; BPMPLO7325Z;
BPMPLO116M-N; BPMPLO120M-N; BPMPLO125M-N; BPMPLO130M-N; BPMPLO216M-N; BPMPLO220M-N; BPMPLO225M-N; BPMPLO230M-N; BPMPLO316M-N; BPMPLO320M-N; BPMPLO325M-N; BPMPLO330M-N; BPMPLO316W-N; BPMPLO3120W-N; BPMPLO3125W-N; BPMPLO3130W-N; BPMPLO3216W-N; BPMPLO3220W-N; BPMPLO3225W-N; BPMPLO3230W-N; BPMPLO3316W-N; BPMPLO3320W-N; BPMPLO3325W-N; BPMPLO3330W-N; BPMPLO7116Z-N; BPMPLO7120Z-N; BPMPLO7125Z-N; BPMPLO7130Z-N; BPMPLO7216Z-N; BPMPLO7220Z-N; BPMPLO7225Z-N; BPMPLO7316Z-N; BPMPLO7320Z-N; BPMPLO7325Z-N; BPMPLO7325Z-N;

BionMET CC

BTC0180M; BTC0190M; BTC0200M; BTC0210M; BTC0220M; BTC0230M; BTC0240W; BTC0250W; BTC0260W; BTC0270W; BTC0280W; BTC0290W; BTC0300W; BTC0421W; BTC0431W; BTC0500Z; BTC0510Z; BTC0520Z; BTC0530Z; BTC0540Z; BTC0550Z; BTC0560Z; BTC0570Z; BTC0590Z;
BTC0180M-N; BTC0190M-N; BTC0200M-N; BTC0210M-N; BTC0220M-N; BTC0230M-N; BTC0240W-N; BTC0250W-N; BTC0260W-N; BTC0270W-N; BTC0280W-N; BTC0290W-N; BTC0300W-N; BTC0421W-N; BTC0431W-N; BTC0500Z-N; BTC0510Z-N; BTC0520Z-N; BTC0530Z-N; BTC0540Z-N; BTC0550Z-N; BTC0560Z-N; BTC0570Z-N; BTC0590Z-N;

BionMET T2

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BTB0180M-N; BTB0190M-N; BTB0200M-N; BTB0210M-N; BTB0220M-N; BTB0230M-N; BTB0240W-N; BTB0250W-N; BTB0260W-N; BTB0270W-N; BTB0280W-N; BTB0290W-N; BTB0300W-N; BTB0421W-N; BTB0431W-N; BTB0500Z-N; BTB0510Z-N; BTB0520Z-N; BTB0530Z-N; BTB0540Z-N; BTB0550Z-N; BTB0560Z-N; BTB0570Z-N; BTB0590Z-N;

BionMET T4

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BTD0180M-N; BTD0190M-N; BTD0200M-N; BTD0210M-N; BTD0220M-N; BTD0230M-N; BTD0240W-N; BTD0250W-N; BTD0260W-N; BTD0270W-N; BTD0280W-N; BTD0290W-N; BTD0300W-N; BTD0421W-N; BTD0431W-N; BTD0500Z-N; BTD0510Z-N; BTD0520Z-N; BTD0530Z-N; BTD0540Z-N; BTD0550Z-N; BTD0560Z-N; BTD0570Z-N; BTD0590Z-N;

BionMET T5

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BTE0180M-N; BTE0190M-N; BTE0200M-N; BTE0210M-N; BTE0220M-N; BTE0230M-N; BTE0240W-N; BTE0250W-N; BTE0260W-N; BTE0270W-N; BTE0280W-N; BTE0290W-N; BTE0300W-N; BTE0421W-N; BTE0431W-N; BTE0500Z-N; BTE0510Z-N; BTE0520Z-N; BTE0530Z-N; BTE0540Z-N; BTE0550Z-N; BTE0560Z-N; BTE0570Z-N; BTE0590Z-N;

Ort und Datum:
Luogo e data:
Place and date:
Date et lieu:

Brunico, 03.05.2024

Direktor - Direttore:
Director - Directeur:

Name - Nome - Name - Nom: Pfeifhofer Paul
Unterschrift - Firma - Signature - Signature:

