



Declaration of Conformity

Manufacturer: The Argen Corporation, 5855 Oberlin Drive, San Diego, CA 92121

EC Representative: Medical Device Safety Service GmbH,
Schiffgraben 41, D-30175 Hannover,
Germany

Notified Body: BSI Group The Netherlands B.V. Say Building
John M. Keynesplein 9, 1066 EP Amsterdam (CE2797)

CE Certificate: 542249

Intended Use: Design, development and manufacturer of alloys and ceramics used in
fixed and removable dental prosthetics

The Argen Corporation, located at 5855 Oberlin Drive, San Diego, CA 92121-4718
declares, under our sole responsibility, the following dental products:

AG AUROR
AG BIO PLATINUM
AG CERAMIK 38
AG CERAMIK N
AG CERANORM PKF
AG UNIPAL
ARGEDENT 54
ARGEDENT 60SF
ARGEDENT 65SF
ARGEDENT 74
ARGEDENT 75
ARGEDENT 76
ARGEDENT 87
ARGEDENT 90
ARGEDENT AH

CONFORMITY ASSESSMENT		
Device Classification	Route to Compliance	Edition/ Date of issue
<i>Class IIa Rule 8</i>	<i>Annex II, Article 3 of MDD 93/42/EEC Council Directive and applicable requirements of amendment 2007/47/EC (Full Quality Assurance - No. CE 542249)</i>	<i>1993</i>

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ARGEDENT AR208
ARGEDENT BIO 720PF
ARGEDENT BIO 78PF
ARGEDENT BIO 82
ARGEDENT BIO 860Y
ARGEDENT BIO 862PF
ARGEDENT BIO 86PF
ARGEDENT BIO 880PF
ARGEDENT BIO 89PF
ARGEDENT BIO SMILE
ARGEDENT BIO YELLOW PF
ARGEDENT EURO
ARGEDENT HN
ARGEDENT K
ARGEDENT LIBERTY
ARGEDENT PM-5
ARGEDENT QUEEN 56
ARGEDENT SUPER 40
ARGEDENT TRENDY
ARGEDENT ULTRA SPEC
ARGEDENT Y73
ARGEDENT Y86
ARGEDENT YELLOW 2
ARGELITE 2
ARGELITE 49
ARGELITE 50

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ARGELITE 52+
ARGELITE 54+
ARGELITE 54B
ARGELITE 55
ARGELITE 57
ARGELITE 57+
ARGELITE 58P
ARGELITE 59
ARGELITE 60
ARGELITE 61
ARGELITE 61+3
ARGELITE 63+4
ARGELITE 70+
ARGELITE 71
ARGELITE 75+6
ARGELITE 76SF+
ARGELITE 80SF+
ARGELITE 81SF+
ARGELITE PF+
ARGELOY 280
ARGELOY C ARGELOY
LFC ARGELOY N.P. (Be-
Free) ARGELOY N.P.
APEX
ARGELOY N.P. CB WHITE
ARGELOY N.P. ELITE

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ARGELOY N.P. PARTIAL
 ARGELOY N.P. PREMIER
 ARGELOY N.P. PRIME
 ARGELOY N.P. SPECIAL
 ARGELOY N.P. STAR
 ARGELOY N.P. SUPREME
 ARGELOY PARTIAL
 ARGELOY PARTIAL +
 ARGELOY PARTIAL EXTRA
 ARGELOY PARTIAL HARD
 ARGELOY PARTIAL PLUS
 ARGELOY SUNRAY
 ARGENCO 10
 ARGENCO 10S
 ARGENCO 12
 ARGENCO 18
 ARGENCO 20
 ARGENCO 24
 ARGENCO 25
 ARGENCO 26
 ARGENCO 333
 ARGENCO 33KF
 ARGENCO 34
 ARGENCO 4
 ARGENCO 40
 ARGENCO 40Y

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ARGENCO 41
 ARGENCO 42
 ARGENCO 43
 ARGENCO 46
 ARGENCO 5
 ARGENCO 50
 ARGENCO 50 IV
 ARGENCO 52
 ARGENCO 56
 ARGENCO 58
 ARGENCO 60
 ARGENCO 60 (TYPE III)
 ARGENCO 60M
 ARGENCO 60S
 ARGENCO 62
 ARGENCO 63
 ARGENCO 68
 ARGENCO 75
 ARGENCO 75 SA
 ARGENCO 75M
 ARGENCO 7A
 ARGENCO 83
 ARGENCO 879
 ARGENCO 883KF
 ARGENCO A3
 ARGENCO AR-K14

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ARGENCO AR-K18
 ARGENCO AR-K20
 ARGENCO Au2
 ARGENCO BESTCAST
 ARGENCO BIO 1
 ARGENCO BIO 2
 ARGENCO BIO 3
 ARGENCO BIO 7
 ARGENCO BIO LIGHT
 ARGENCO CAST FIT
 ARGENCO ECO
 ARGENCO GK
 ARGENCO High Purity 77 (ARGENCO HP 77)
 ARGENCO M1
 ARGENCO SUN KF
 ARGENCO W
 ARGENCO W+
 ARGENCO WLF
 ARGENCO W-LITE
 ARGENCO WR+
 ARGENCO Y+
 ARGENCoCr 255
 ARGENCoCr 275
 ArgenZ Anterior
 (Shades: White, #1, #2, #3, #4, #5, #6)
 ArgenZ Color Modifiers
 (Shades: Orange, Yellow, White, Violet, Gray, Brown, Blue)

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ArgenZ Esthetic

(Shades: White, A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, OM2)

ArgenZ HT+ Multilayer (ML)

(Shades: A1, A1-L, A2, A2-L, A3, A3.5, A4, B1, B1-L, B2, B3, B4, C1, C1-L, C2, C3, C4, D2, D2-L, D3, D4, OM1, OM2, OM3)

ArgenZ HT+

(Shades: White, A1, A1-L, A2, A2-L, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, OM1, OM2, OM3)

ArgenZ Incisal (Effect 1, Effect 2, Effect 3)

ArgenZ Liquid Shades HT (HT A1 S, HT A2 S, HT A3 S, HT A3.5 S, HT A4 S, HT B1 S, HT B2 S, HT B3 S, HT B4 S, HT C1 S, HT C2 S, HT C3 S, HT C4 S, HT D2 S, HT D3 S, HT D4 S, HT OM1 S, HT OM2 S, HT OM3 S)

ArgenZ Liquid Shades ST (ST A1 S, ST A2 S, ST A3 S, ST A3.5 S, ST A4 S, ST B1 S, ST B2 S, ST B3 S, ST B4 S, ST C1 S, ST C2 S, ST C3 S, ST C4 S, ST D2 S, ST D3 S, ST D4 S)

ArgenZ Pontic Reducer

ArgenZ ST Multilayer (ML)

(Shades: White, A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, OM1, OM2, OM3)

ArgenZ Tissue (Shades: Pink, Light Pink, Dark Pink)

ArgenZ Ultra

ARGESOL LO

ARGESOL 1030PF

ARGESOL 585

ARGESOL 615

ARGESOL 650

ARGESOL 690PF

ARGESOL 710PF

ARGESOL 725M

ARGESOL 750W

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ARGESOL 750Y
ARGESOL 800PF
ARGESOL 810PF
ARGESOL 830Y
ARGESOL 870PF
ARGESOL 950PF
ARGESOL 960PF
ARGESOL 980
ARGESOL PNP
ARGESOL PNP 950
ARGESOL W
ARGESOL W PRE
ARGESOL WSF
ARGESOL YPF
ARGESOL YSF
ARGICAST B
ARGICRAFT 2
ARGINORM
ARGIPLUS 2
ARGISAFE 26
ARGISAFE 37P
ARGISAFE 38
ARGISAFE 40
ARGISAFE 550
ARGISAFE 570
ARGISAFE 58P

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ARGISAFE 63+4
 ARGISTAR 37
 ARGISTAR 38
 ARGISTAR 40
 ARGISTAR 43+
 ARGISTAR 545
 ARGISTAR 550
 ARGISTAR 570
 ARGISTAR 580
 ARGISTAR 598
 ARGISTAR 73
 ARGISTAR BIO 69
 ARGISTAR BIO 727
 ARGISTAR BIO 738
 ARGISTAR BIO 75PF
 ARGISTAR E
 ARGISTAR EH
 ARGISTAR SUN
 ARGISTAR YELLOW LF
 AURO AF 1
 AURO BOND 4
 AURO DUO N2
 AURO DUR II
 AURO E4
 AURO NF IV
 AUROLOR M

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BELLADENT BIO SG
BELLADENT U PLUS
BIOLITE 7.1
BIOPLATINUM HT 2.0
BIOSTAR LF 4.0
CLASP WIRE
Co WELDING ROD Ni Free
Co/Cr LW
Co/Cr NP PRE
Co/Cr NP Pre Solder
Co/Cr Pre
Co/Cr Wire
CoCr 255
CoCr 275
Eurodent B X
Eurodent PB V
Eurodent PC 10
Eurodent PC 18
Eurodent PC 2
Eurodent PC 26
Eurodent PC NP SP
FLEMMING BIO 2
FLEMMING BIO 86PF
FLEMMING BIO SMILE
FLEMMING BIOSTAR 727
FLEMMING GOLD 7A

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FLEMMING HP 77
 FLEMMING NORM
 FLEMMING STAR 545
 Flux n Sol
 FULL ROUND WIRE
 GOLDTECH BIO 2000
 GOLDTECH SOLDER
 HALF ROUND WIRE
 HIGH PURITY 77
 LASER WIRE
 Laserdraht 0.4mm
 LITE
 LO
 LO SOLDER
 LWL 54
 LWL 58
 LWL 60
 LWL 75
 LWNPCO
 LWNPNI
 LWO 33
 LWO 56
 LWO 72
 LWO 75
 LWO 77
 LWS 38

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LWS 40
LWS 73
LWT 40
LWT 52
LWT 52SF
LWT 65
LWT 720PF
LWT 77
LWT 80
LWT 84
LWT 86
LWT 87
LWT 88
MAXIBOND 2
MEDOH BIO PDF
Ni/Cr Wire
NOBLEBOND
NOBLECROWN
NOBLECROWN NF
NOVABOND
NP SOLDER
NP SOLDER Ni/Cr
OLYMPIA
P
P PRE SOLDER
PHASER 52

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PHASER 52SF
 PHASER 80
 PHASER 84
 Phaser Ni/Cr LW
 PHASER NP Co/Cr
 PHASER NP Ni/Cr
 PHASER PHO75
 Platinum Plus
 PNP
 PNP 950
 SCHERZ TS. BIO 1
 Select Lot/NF
 Select Lot/Ni
 Selector II
 SG BIO NORM
 SLM NOBLECROWN NF
 SLM NP PARTIAL
 SLM Premier Powder
 SLM SUPREME
 STAHLGOLDLOT 750
 SUPER CLASP WIRE
 SUPRACHROME
 SUPRACHROME +
 Tek-1 Leg
 TOPCAST
 TRIPLE THICK SOLDER

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UNIPAL YELLOW

V-Alloy FG

vierQ Basic vierQ

Bio Platin vierQ

Classic Gold W

W PRE

W PRE SOLDER

WSF

XENTAL CONCEPT 75PF

XENTAL PAL G

XENTAL S-P UNI

XENTAL UNI PLUS

YELLOW SPECIAL

YPF

YSF

YSF SOLDER

Zirconia Incisal/Zr Incisal
(Shades: 1,2,3)

ZirconiaColor Modifier/Zr Color Modifier/Color Modifier
(Shades: Orange, Yellow, White, Violet, Gray, Brown, Blue)

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comply with the legislation of the United Kingdom, transposing European Medical Device Directive 93/42/EEC.

San Diego, California May 13, 2024
(Place and Date of Issue)

On behalf of Shilpi Sinha,
Sr. Director, Quality and Regulatory Affairs & PRRC

Trish Ly
Senior Regulatory Affairs Specialist
(Name, Function)

(Signature)

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