DECLARATION OF CONFORMITY

MANUFACTURER

KCI USA, Inc.
12930 IH10 West
San Antonio, TX 78249
U.S.A.

KCI USA, Inc. declares that the products herewith comply with the requirements of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC and the Medical Devices (Amendment) Regulation 2008 no. 2936 and carry the CE mark accordingly.

PRODUCT IDENTIFICATION

InfoV.A.C./V.A.C. Ulta 500mL Canisters with gel, REF M8275063/5, M8275063/10, M8275063/1
InfoV.A.C./V.A.C. Ulta 500mL Canisters without gel, REF M8275071/5, M8275071/10
InfoV.A.C./V.A.C. Ulta 1000mL Canister with gel, REF M8275093/5

AUTHORIZED REPRESENTATIVE

KCI Medical Products (UK), Ltd.
Wimborne, Dorset
BH21 7SH
United Kingdom

REGISTRATION INFORMATION

Notified body/ID#	**CE Certificate Number**
AMTAC/0473	674-01 A CE

CONFORMITY ASSESSMENT

Device Classification	**Route to Compliance**
Class IIb Rule 4	Annex II (excluding section 4) of the Medical Device Directive 93/42/EEC Council directive as amended by Directive 2007/47/EC

Signed for and on behalf of KCI USA, Inc.,

Veronique Smith
Senior Director, Regulatory Affairs
San Antonio, Texas, U.S.A.

May 22, 2015
Date of Issue

REPUBLICA MOLDOVA, mun. CHISINAU
S.R.L. «MT INTERNATIONAL GROUP»
IDNO 1015600021387
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

Digitally signed by Kalcev Ghennadi
Date: 2019.03.20 16:22:47 EET
Reason: MoldSign Signature
Location: Moldova

DECLARATION OF CONFORMITY

An Acelity Company

MANUFACTURER

KCI USA, Inc.
12930 IH10 West
San Antonio, TX
78249
USA

Initial Issue Date: July 17, 2018 Revision: A
Re-Issue Date: N/A Revision: N/A

MANUFACTURING SITE

Contract Manufacturing Facility for the V.A.C.® GRANUFOAM SILVER™ Dressing:

KCI Manufacturing
IDA Business & Technology Park
Dublin Road, Athlone
Ireland

Foam Supplier:

FXI (formerly Foamex Innovations Operating Company)
3005 Commercial road
Fort Wayne, IN 46809 USA

Silver Coating Facility:

Noble Biomaterials, Inc.
300 Palm Street
Scranton, PN 18505 USA

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PRODUCT IDENTIFICATION

V.A.C.® GRANUFOAM SILVER™ Dressing -Small featuring SensaT.R.A.C. Technology
M8275098/5 5-pack
M8275098/10 10-pack

V.A.C.® GRANUFOAM SILVER™ Dressing -Medium featuring SensaT.R.A.C. Technology
M8275096/5 5-pack
M8275096/10 10-pack

V.A.C.® GRANUFOAM SILVER™ Dressing - Large featuring SensaT.R.A.C. Technology
M8275099/5 5-pack
M8275099/10 10-pack

AUTHORIZED REPRESENTATIVE

KCI Manufacturing Unlimited Company
IDA Business & Technology Park
Dublin Road
Athlone, Co. Westmeath, Ireland

REGISTRATION INFORMATION

KCI
An Acelity Company

DECLARATION OF CONFORMITY

BSI Kitemark Court Davy Avenue Knowlhill Milton Keynes MK5 8PP United Kingdom Notified Body Identification Number: 0086	**EC Certificate Number** CE 661656 **EC Design Examination Certificate Number** CE 673268
CONFORMITY ASSESSMENT	
Device Classification Class III Rule 13	**Route to Compliance** Annex II (including section 4) of the Medical Device Directive 93/42/EEC Council directive

Signed for and on behalf of KCI USA, Inc.,

Anona Goebel

Anona Goebel, Director Regulatory Affairs
San Antonio, Texas, U.S.A.

17 July 2018
Date of Issue

REPUBLICA MOLDOVA, mun. CHIȘINĂU
S.R.L.
«MT INTERNATIONAL GROUP»
IDNO 1015600021387
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

DECLARATION OF CONFORMITY

MANUFACTURER

KCI USA, Inc.
12930 IH10 West
San Antonio, TX 78249
U.S.A.

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PRODUCT IDENTIFICATION

V.A.C.® GranuFoam™ Dressings *featuring SensaT.R.A.C.™ Technology*

M8275051/5 and M8275051/10 V.A.C.® GranuFoam™ Dressing Small
M8275052/5 and M8275052/10 V.A.C.® GranuFoam™ Dressing Medium
M8275053/5 and M8275053/10 V.A.C.® GranuFoam™ Dressing Large
M8275065/5 V.A.C.® GranuFoam™ Dressing X- Large
M8275075/5 and M8275075/10 V.A.C.® GranuFoam™ Dressing Round
M8275081/5 and M8275081/10 V.A.C.® GranuFoam™ Thin Dressing

AUTHORIZED REPRESENTATIVE

KCI Medical Products (UK), Ltd.
Wimborne, Dorset
BH21 7SH
United Kingdom

REGISTRATION INFORMATION

Notified body/ID#	***CE Certificate Number***
AMTAC/0473	674-01 A CE

CONFORMITY ASSESSMENT

Device Classification	**Route to Compliance**
Class IIb Rule 4	Annex II (excluding section 4) of the Medical Device Directive 93/42/EEC Council directive

Signed for and on behalf of KCI USA, Inc., San Antonio, Texas, U.S.A.

Veronique Smith
Senior Director, Regulatory Affairs

April 20, 2015
Date of Issue

REPUBLICA MOLDOVA, mun. CHIŞINĂU
S.R.L. «MT INTERNATIONAL GROUP»
IDNO 1015600021387
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

DECLARATION OF CONFORMITY

MANUFACTURER

KCI USA, Inc.
12930 IH 10 West
San Antonio, TX 78249
U.S.A.

KCI USA, Inc. declares that the products herewith comply with the requirements of the Council Directive 93/42/EEC as amended by directive 2007/47/EC and the Medical Devices (Amendment) Regulation 2008 no. 2936 and carry the CE mark accordingly.

PRODUCT IDENTIFICATION

Sterile V.A.C.® Disposable Accessories

V.A.C.® Drape - M6275009/10
SensaT.R.A.C.™ Pad featuring SensaT.R.A.C.™ Technology – M8275057/10
V.A.C.® Y-Connector – M6275066/5 and M6275066/10

AUTHORIZED REPRESENTATIVE

KCI Medical Products (UK), Ltd.
Wimborne, Dorset
BH21 7SH
United Kingdom

REGISTRATION INFORMATION

Notified body/ID#	**CE Certificate Number**
AMTAC/0473	674-01 A CE

CONFORMITY ASSESSMENT

Device Classification	**Route to Compliance**
Class IIb Rule 4	Annex II (excluding section 4) of the Medical Device Directive 93/42/EEC Council directive

Signed for and on behalf of KCI USA, Inc. San Antonio, Texas, U.S.A.

Veronique Smith, Senior Director, Regulatory Affairs

March 16 2015
Date of Issue

REPUBLICA MOLDOVA, mun. CHIȘINĂU
S.R.L.
«MT INTERNATIONAL GROUP»
IDNO 1015600021387
SOCIETATEA CU RĂSPUNDERE LIMITATĂ