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

V.A.C.Ulta™ Unit- ULTDEV01/UK (UK/Ireland), ULTDEV01/EU (Estonia), ULTDEV01/DE (Germany/Austria/Luxemburg), ULTDEV01/FR (France), ULTDEV01/ES (Spain), ULTDEV01/BE (Belgium), ULTDEV01/NL (Netherlands), ULTDEV01/IT (Italy), ULTDEV01/CH (Switzerland), ULTDEV01/GR (Greece), ULTDEV01/SE (Sweden), ULTDEV01/DK (Denmark), ULTDEV01/FI (Finland), ULTDEV01/NO (Norway), ULTDEV01/TR (Turkey), CAPULTDEV01/CZ (Czech Republic), CAPULTDEV01/HR (Croatia), CAPULTDEV01/HU (Hungary), CAPULTDEV01/SK (Slovakia), CAPULTDEV01/PL (Poland), CAPULTDEV01/SI (Slovenia), CAPULTDEV01/RO (Romania), HCULTDEV01/FR (Home Use – France)
V.A.C. VeraLink™ Cassette 5-pack- ULTLNK0500 and **1-pack** –ULTLNK0100
V.A.C. VeraFlo™ Dressing System- Medium 5-pack- ULTVFL05MD and ULTVFL05MD/NSP (Nordic part number) and **1-pack** -ULTVFL01MD
V.A.C. VeraFlo™ Dressing System- Small 5-pack- ULTVFL05SM, ULTVFL05SM/NSP (Nordic part number) and **1-pack**-ULTVFL01SM
V.A.C. VeraFlo™ Dressing System – Large 5-pack- ULTVFL05LG, ULTVFL05LG/NSP (Nordic part number) and **1-pack** – ULTVFL01LG
V.A.C. VeraFlo Cleanse™ Dressing System 5 pack- ULTVCL05MD ULTVCL05MD/NSP (Nordic part number) and **1-pack** –ULTVCL01MD
V.A.C. VeraFlo Cleanse™ Choice Dressing System 5 pack- ULTVCC05MD (UK and Ireland only)
V.A.C. VeraTRAC™ Duo Tube Set 5 pack - ULTDUO0500 and **1-pack** ULTDUO0100

AUTHORIZED REPRESENTATIVE

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

REGISTRATION INFORMATION

Notified body/ID#	**CE Certificate Number**
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.,

Melanie Avila
Senior Manager, Regulatory Affairs
San Antonio, Texas, U.S.A.

July 13, 2015
Date of Issue

Digitally signed by Kalcev Gennadi
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