silc® S.p.A.

CE Conformity Certificate

S.I.L.C. S.p.A. , Strada Provinciale no.35 , km.4 , 26017 Trescore Cremasco (Cremona - Italy) guarantees and certifies that all its **products for adult incontinence** belonging to the not sterile class I, satisfy the requisites set forth in the Directive of the Council 93/42/EEC of June 14, 1993 concerning medical devices, as published in the Official Gazette on July 12, 1993 and in the Italian Legislative Decree no.46 of February 24, 1997, as published in the Official Gazette on March 6, 1997.

Complying with art. 13, par. 1 of Italian Legislative Decree no.46, S.I.L.C. has sent request for the registration to the Ministry of Health in Rome, sending address and medical devices description.

Compiled by : Mrs Lucia Donarini

in charge of compliance with standards and drawing up the supporting documentation

Signed : Donarini Lucia Date : April 29, 2002

Approved by : Mr Amelio Arcelloni

Chairman

Signed : Amelio Arcelloni Date : April 29, 2002

1/1

Kopie aus Projektordner 134025 2005-03-14 mb

S.p.A.

EC Conformity Declaration

S.I.L.C. S.p.A. , Strada Provinciale no.35 , km.4 , 26017 Trescore Cremasco (Cremona - Italy) declares on its own responsibility that medical device produced, named **SLIP WITH WAIST BELT**, satisfies all the requisites as requested by the Directives of the Council 93/42/EEC and 2007/47/EC and by the Italian Legislative Decrees no.46/97 and no.37/2010, concerning medical devices.

For this purpose S.I.L.C. S.p.A. guarantees and declares on its own responsibility as follow:

- the medical device satisfies all essential requisites set forth in Annex I of the above regulations:
- the medical device belongs to the not sterile class I
- the medical device is sold in not sterile packaging
- the medical device is not a measuring instrument
- the medical device is not intended for clinical studies
- the manufacturer is committed to preserve and make available to health authorities the technical documentation, as specified in Annex VII of the above regulations for 5 years as from the last production date of the item.

S.I.L.C. S.p.A. therefore declares that the device complies with the above regulations and will be marketed with the CE marking according to the Art.17 of Directive of the Council 93/42/EEC and to the Art.16 of the Italian Legislative Decree no.46/97.

Approved by : Mr. Cesare Battaglia

Managing Director

Signed : Date : 02.05.12