

		 MedExel (주)메덱셀 Medexel Co., Ltd. #252, GEUMGWANGOSAN-RO, GEUMGWANG-MYEON, ANSEONG-SI, GYEONGGI-DO, KOREA. TEL 82-31-677-8004, FAX 82-31-677-8007, http://www.medexel.co.kr		
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DECLARATION OF CONFORMITY

We, MedExel Co., Ltd.

declares under our sole responsibility that the below mentioned products
Sterile single-use Insulin Pen needles

(Sterile single-use Insulin Pen Needles 29G (0.33mm)) X10 mm, 12mm, 12.7mm

(Sterile single-use Insulin Pen Needles 30G (0.30mm)) X 8mm

(Sterile single-use Insulin Pen Needles 31G (0.25mm)) X 5mm, 6mm, 8mm

(Sterile single-use Insulin Pen Needles 32G (0.23mm)) X 4mm, 5mm, 6mm

(Sterile single-use Insulin Pen Needles 33G (0.20mm)) X 4mm, 5mm, 8 mm

(Sterile single-use Insulin Pen Needles 34G (0.18mm)) X 4mm, 5mm, 8 mm

Brand: Top fine®, KLINION Soft Fine® plus, CareSens, DL, WellFine®

are in conformity with the essential requirement and provisions of
Council Directive 93/42/EEC & ISO 7864, ISO11608-2

In addition, the class of above medical devices is Class II a as per MDD/93/42/EEC
(ANNEX IX, Rule 6).

is subject to the procedure set out in Annex II (excluding section 4) of Directive
93/42/EEC under the supervision of Notified Body Number 0120,
SGS UK Ltd. ICS Unit 202B, Worle Parkway Weston-Super-Mare North
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President : Dong ik, Cha / January, 20. 2016