



#301, 464, Dunchon-daero, Jungwon-gu, Seongnam-si, Gyeonggi-do, Republic of Korea, 13229
Tel: +82-31-741-0996 / Fax: +82-31-741-0976 / Website: www.rev-med.co.kr

EC Declaration of Conformity

We herewith declare under our sole responsibility that following products meet the provisions of the Council Directive 93/42/EEC and amended by 2007/47/EC concerning medical devices.

Product Name:	Blood Separation Kit
Model Name:	TriCeLL PRP Kit / TriCeLL PRP L / TriCeLL PRP M / TriCeLL PRP S
Relevant EC Directives:	Medical Device Directive 93/42/EEC amended by Directive 2007/47/EC
Conformity Assessment Route:	Annex II excluding Section 4
Classification:	Class IIa according to Rule 3 of Annex IX of 93/42/EEC
Applied Standards:	refer to RM-TCF-01-05
CE Certificate no.:	G1 095551 0002
Valid until:	2023-11-21
Manufacturers Registered Name:	REV-MED Inc.
Manufacturers Registered Address:	#301, 464, Dunchon-daero, Jungwon-gu, Seongnam-si, Gyeonggi-do, Republic of Korea, 13229 Tel: +82 31 741 0996
EC Representative Name:	REV-MED International GmbH
EC Representative Address:	Einsteinstr.167, 81677 Munich, Germany Tel: +49 89 237 625 40, Fax: +49 89 237 625 41
Notified Body:	TÜV SÜD Product Service Ridlerstraße 65, 80339 München, Germany T: +49 89 500 847 47 (Notified Body Identification no.: 0123)
Start of CE-Marking:	2018-11-22

Date: 2018-11-29

CEO of REV-MED Inc.

Shin BongGeun

Republic of Korea