EC DECLARATION OF CONFORMITY

Manufacturer: REV-MED,INC.

Address of Manufacturer: #301 Sangdaewon-dong Joongil Eines Platz) 464 Doonchondaero, Jungwon-gu, Sungnam-city, Kyeonggi-do, Korea

EC Representative: **TEMED**

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Declares that the medical device described here after The PRP Kit device (Model : TriCeLL PRP KIT / TriCeLL BMS KIT / ClonoRegen PRP*)* has been classified as class IIa (Annex IX Rule *3*) and is in conformity with the essential requirements and provisions of Council Directive 93/42/EEC as amended by Directive 2007/47/EC are manufactured within the quality system of ISO13485 and are in conformity with the national standards transposing harmonized standards EN ISO 13485:2012, EN 1041:2008, EN 980:2008, EN ISO 11137-1:2006/A1:2013, EN ISO 11737-1:2006, EN ISO 11737-2:2009, ISO 14644-1:1999, EN ISO 10993-1: 2009, EN ISO 10993-5:2009, ISO 10993-10:2010, EN ISO 10993-11:2009, EN ISO 10993-4:2009, MEDDEV.2.7.1:2009, EN ISO 11607-1:2009, EN ISO 14155:2011 are subject to the procedure set out in Annex II excluding Section 4 of MDD 93/42/EEC as amended by Directive 2007/47/EC under the supervision of Notified Body Number 1023, ITC

(Institute for Testing and Certification, Inc.) Trida T. Bati 299, Louky, 763 02 Zlin, Czech Republic

Date: 31th December 2015

Signature of President

CE 1023

Edware B.Shin