



Declaration of Conformity



According to the In vitro diagnostic medical devices Directive 98/79/EC Annex III

Manufacturer: Asan Pharmaceutical Co., Ltd.

Address 122-26 Gieopdanjio-ro Gongdo-eup Anseong-si Gyeonggi-do, 17551, KOREA

EC Representative: Javier Sánchez,

Address Apartado de correos 5005 Centro Comercial Arroyo Sur 28914 - Leganés (Madrid) Spain

Product : ASAN Helicobacter Test (25, 50 test)

Model name: ASAN Helicobacter Test

Classification : IVD-Others

GMDN code: 06

The product identified above complies with the essential requirements of the above EC Directives by meeting the following standards:

EN ISO 13485:2016, EN ISO 14971:2012, EN 13532:2002, EN 376:2002, EN 1658 : 1996, EN12286:1998, EN 12287:1999, EN 13612:2002, EN13641:2002, EN ISO 15223-1:2012, EN 18113-1:2011, EN 18113-2:2011, EN 18113-3:2011, EN 18113-4:2011, EN 18113-5:2011, EN ISO 18153:2003, EN ISO/IEC 17050-1

Start of CE-marking:

This Declaration of Conformity is based on the directive 98/79/EC, Annex IV Article 4 and 6 Excluded under the supervision of Notified body,

Issue date: 16.05.2017

Yeom, Jeong Gyu, President

Place: *Yeom, Jeong Gyu* Date: 16.05.2017

