ASEL TIBBİ ALETLER SAN. VE TİC. A.Ş.
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Date: 21.08.2019

MANUFACTURERS' DECLARATION

Manufacturer: Asel Tıbbi Aletler San. Tic. A.Ş.

Product: Re-usable Surgical Instruments

We declare under our sole responsibility that the medical device of class I, to which this declaration relates are in conformity with the provisions of the Council Directive 93/42/EEC (2007/47/EC). Each kind of medical device to which the Full Quality Assurance Procedures have been applied complies device to which the Full Quality Assurance Procedures have been applied complies with the applicable provisions of the essential principles, the classification rules, at each stage, from the design of the device until its final inspection before being supplied. The medical devices are in conformity with the essential requirements of Annex I of the EEC directive. The conformity assessment procedure was performed according to Annex VII of the EEC directive.

Standards and Directives Applied:

93 /42/EC	EN ISO 13485:2016	IEC 62366-1:2015	EN ISO 11607-2:2019
EN ISO 15223-1:2016	EN ISO 14971:2012	EN ISO 11607-1:2019	EN 1041+A1:2013
ISO 00780-2015	ISO 07151-1998	ISO 07153-1-2016	ISO 07740-1985
ISO 07741-1986	ISO 10993-1-2018	ISO 13402-1995	DIN 58298
MEDDEV 2.7.1	MEDDEV 2.12-1	MEDDEV 2.12-2	EN 868-8:2009
ISO 11737-2:2009	EN 285:2015	EN ISO 17664:2017	EN ISO 17665-1:2006
ISO 17665-1:2006	ISO 18472:2018	EN ISO 11140-1:2014	

Hakan Günseli – General Manager

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