



Afa INDUSTRIES MED LTD.

Add: 4F., NO. 190, JIANGUO RD., YINGGE DIST., NEW TAIPEI CITY 239, TAIWAN
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Date: July 28th 2017

DECLARATION OF CONFORMITY

We, AFA INDUSTRIES MED LTD. of 4F., NO 190, Jianguo Rd., Yingge Dist., New Taipei City 239, Taiwan, as the legal manufacturer (product owner) undersigned hereby declares that the products described below is herewith confirmed to comply with the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning **Medical Device Directive 93/42/EEC As Amended by 2007/47/EC** with the compliance of conformity assessment Annex VII.

The products Classification by ANNEX IX OF Medical Device Directive 93/42/EEC

NAME OF PRODUCT	Products	Classification
AUTOCLAVE	EX-SERIES TABLETOP AUTOCLAVE HX-SERIES TABLETOP AUTOCLAVE LX-SERIES TABLETOP AUTOCLAVE NX-SERIES TABLETOP AUTOCLAVE VB-SERIES STEAM STERILIZERS VP-SERIES STEAM STERILIZERS ECO PLUS SERIES HORIZONTAL AUTOCLAVE ECO-SERIES HORIZONTAL AUTOCLAVE KE-SERIES STAND AUTOCLAVE KNIGHT-SERIES STAND AUTOCLAVE TP-SERIES STAND AUTOCLAVE	Class II a
OPERATING TABLE	AT-160 ORTHOPEDIC EXTENSION TRACTOR AT-600 DELUXE MULTI-FUNCTION HYDRAULIC OPERATION TABLE AT-700 SERIES OPHTHALMIC & PLASTIC OPERATION TABLE AT-800E FULLY ELECTRIC MULTI-PURPOSE OPERATING TABLE AT-800 SERIES MULTI PURPOSE SEMI-ELECTRIC OPERATION TABLE AT-80 UNIVERSAL HYDRAULIC OPERATING TABLE AT-900 SERIES ELECTRIC OPERATION TABLE AT-90 UNIVERSAL HYDRAULIC OPERATING TABLE AT-95 UNIVERSAL HYDRAULIC OPERATING TABLE	Class I
GYNECO TABLE	AG-300 SERIES, GYNECOLOGICAL EXAMINATION AND OBSTETRIC TABLE AG-600 SERIES OBSTETRIC DELIVERY & OPERATION TABLE AG-800 MULTI-PURPOSE GYNECOLOGICAL OBSTETRIC &	Class I

OPERATION TABLE		
OPERATING LIGHT	ALA-01 HALOGEN EXAMINATION AND OPERATION LAMP ALA-02 LED EXAMINATION AND OPERATION LAMP K3-SERIES LED OPERATION LAMP K6-SERIES LED OPERATION LAMP ALB SPARK SERIES OPERATION LAMP ALA UNIVERSE SERIES OPERATION AND EXAMINATION LAMP	Class I
SUCTION UNIT	AC-100 CONVENIENT PORTABLE SUCTION UNIT AC-200 SERIES PORTABLE SUCTION UNIT AC-80 AMBULANCE & PORTABLE SUCTION UNIT AC-300 SUPER SURGICAL SUCTION UNIT AC-310 SUPER SURGICAL SUCTION UNIT AC-320 SUPER SURGICAL SUCTION UNIT AC-500 SURGICAL & GYNECOLOGICAL SUCTION UNIT AC-510 SURGICAL & GYNECOLOGICAL SUCTION UNIT AC-520 SURGICAL & GYNECOLOGICAL SUCTION UNIT AC-600 GASTRIC-THORACIC DRAINAGE PUMP	Class II a
AMBU EQUIPMENT	AD-800 AUTOMATIC LOADING STRETCHER AD-801 LIGHT AUTOMATIC LOADING STRETCHER AD-850 CONVENIENT CARRY CHAIR	Class I
TREATMENT UNIT	AD-900 EMERGENCY TREATMENT UNIT AN-100 COMPACT E.N.T. TREATMENT UNIT	Class I

AFa Industries Med Ltd.

Huang Chin-Jui

HUANG, CHIN-JUI

Director

