M.S.D.N: 0109710826 - C.T.C.P
CÔNG TY CỔ PHẦN NOVAMED VIỆT NAM
THÀNH PHỐ HÀ NỘI

DECLARATION OF CONFORMITY
TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES

MANUFACTURER: SHENZHEN INSIGHTERS MEDICAL TECHNOLOGY CO.,LTD.
THE 13TH FLOOR OF HENGTEMEI BUILDING, GANLI ROAD NO.3, 518000
SHENZHEN, GUANGDONG, PEOPLE'S REPUBLIC OF CHINA

MEDICAL DEVICE: INSIGHT WORKSTATION
MODEL: IS-PF1, IS-PF2

CLASSIFICATION - ANNEX IX: CLASS I, RULE 13

CONFORMITY ASSESSMENT ROUTE: ANNEX II EXCLUDING (4)

WE, SHENZHEN INSIGHTERS MEDICAL TECHNOLOGY CO.,LTD. , HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES; INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC. ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER. WE ARE EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

STANDARDS APPLIED:
EN ISO 13485:2016; EN ISO 14971:2012; EN 1041:2008+A1:2013; EN ISO 15223-1:2016; EN 60601-1:2006+A1:2013; EN 60601-1-2:2015; EN 62304:2006+A1:2015; EN 60601-1-6:2010+A1:2015; EN 62366-1:2015

CE

START OF CE-MARKING: 2019-07-03

PLACE, DATE OF DECLARATION: *CITY, DATE* Shenzhen, China 2019.7.8

SIGNATURE:

NAME:

POSITION: (RESPONSIBLE SENIOR EXECUTIVE OF MANUFACTURER)