

**KONFORMITÄTSERKLÄRUNG / DECLARATION DE CONFORMITE
DECLARATION OF CONFORMITY / DICHIARAZIONE DI CONFORMITA**

Name und Adresse der Firma
Nom et adresse de l'entreprise
Nome e indirizzo della ditta
Name and address of the firm

SHANDONG PING AN YONGTAI CO., LTD

East of Jinling street, Lingcheng Town, Qufu city,

Shandong Province, China .

Wir erklären in alleiniger Verantwortung, dass / Nous déclarons sous notre propre responsabilité que /Dichiariamo sotto
nostra responsabilità che / We declare under our sole responsibility that

Product Name

Operating light, Operating table, Hospital bed

EU REPRESENTATIVE :

SUNGO EUROPE B.V

Olympisch Stadion 24, 1076DE, Amsterdam, Netherlands

SRN : NL-AR-000000247

das Medizinprodukt
le dispositif médical
the medical device
il dispositivo medico

YDZ700/500,YDZ700/700,YDZ500/500,YDZ700,YDZ500, YDZ 500D,
DW500/700,DW500,DW500/500,DW700, DW300,
YDE700/500,YDE700/700,YDE500/500,DW700/500,YDE700,YDE700D,Y
DE500, YDE 500D,YDE 300,YDE300D, DST-1, DST-1A, DST-II, DSTIII,
DST-500, DST-500A,DST-700,DST-700G,DST-700T,DST-700Q,JR-
9000,DST-IV, DST-3003,DST-IVA,DST-3004,DST-V,DFC-6001,DHC-
IV(FG05), DHC- III(FM05),DHC-III(FM04),DHC-II(FM03),FN-2,FN-1,DHC-
II(FO03), DHC-
III(FP04), DHC-II(FP03),FO-1.FO-2.FO-2-H.FO-6.FO-7.FO-8.FO-9, FP-1,
FP-2, FP-6,FP-7,FP-8,FP-9, FA-1,FA-2, FA-3, FA-4, FA-5, FA-6, FA-7,
FA-8, PE-3, PE-4, PE-5,PE-6,PE-7,PE-8,PE-9,PE-10,PE-11, PE-12,
PE-16, , FN-1, FP-1, FP-8, FP-9, FC-1, FD-1, FF-1, FG-I, , FB-1,FB-2,
FB-3, FB-4, FC-2,FC-3, FC-4, FD-2, FD-3, FD-4, FE-2, FE-3, FE-4, FF-2,
FF-3,FF-4, FG-2, FG-3, FG-4, FH-2, FH-3, FH-4, A1,A2, A3,A5,A11,
A19,A20, A23, A24, A25,A26,A27,A31,A32,A33, A34, A35, A36, A38,
A39, A39-1, A40, A41,A44,A45

Bezeichnung, Typ oder Modell, Chargen- oder Seriennummer, ev. Herkunft und Stückzahl Nom, type ou modèle, numéro de lot ou série, év. source et nombre d'exemplaires Nome, tipo o modello, numero di lotto o di serie, ev. fonte e numero di esemplari/Name, type or model, batch or serial number, possibly sources and number of items

Class I

der Klasse / de la classe / della classe / of class

Class I, according to Rule 1, Annex VIII, Regulation (EU) 2017/745

allen Anforderungen der Medizinprodukte-Richtlinie Medical Device Regulation (EU) 2017/745 entspricht, die anwendbar sind/ remplit toutes les exigences de la directive sur les dispositifs médicaux Medical Device Regulation (EU) 2017/745 qui le concernent / soddisfa tutte le disposizioni della direttiva Medical Device Regulation (EU) 2017/745 che lo riguardano /meets all the provisions of the directive Medical Device Regulation (EU) 2017/745 which apply to it.

Angewandte harmonisierte Normen, nationale Normen oder andere normative Dokumente

EN 60601-2-38: 1996/A1: 2000

EN60601-1: 1990+A1: 1993+A2: 1995+A13: 1996

EN60601-1-2: 2001

Normes harmonisées, normes nationales et autres documents normatifs appliqués

EN 980: 2003、EN 1041: 1998、

EN ISO 14971: 2000+A1: 2003

Norme armonizzate o nazionali applicate,altri documenti normativi applicati

Applied harmonised standards, national standards or other normative documents

Konformitätsbewertungsverfahren

Procédure d'évaluation de la conformité

Procedimento di valutazione della conformità

Medical Device Regulation (EU) 2017/745

Conformity assessment procedure

Konformitätsbewertungsstelle (falls beigezogen)

Organe resp. de l'évaluat. de la conformité (si consulté) Organo

incaric. della valutaz. della conform. (se consultato) Notified

Body (if consulted)

Ort, Datum / Lieu, date / Luogo, data / Place, date

Name und Funktion / Nom et fonction /Nome e funzione / Name and function
February 20, 2021

WANG WEI

General manager



Wang Wei