

NTLD	HONSUN (Nantong) Co., Ltd.	Version: B
	Declaration of Conformity	Chapter: 01

Manufacturer: HONSUN (Nantong) Co., Ltd.
SRN number: CN-MF-000009428
Address: No.8, Tongxing Road, Economic&Technical Development Area, Nantong City, Jiangsu, P.R.China

EU representative: Shanghai International Trading Corp. GmbH (Hamburg)
SRN number: DE-AR-000000001
Address: Eiffestrasse 80, 20537 Hamburg, Germany

Product: Penlight
UMDNS code: 12276
Model: HS-401F,HS-401F1,HS-401F2,HS-403F3,HS-401F5,HS-401F6,HS-401F8,HS-401F9,HS-401F12,HS-401F13,HS-401F14,HS-402,HS-401H2,HS-401F3-B,HS-402F13-B,H S-402F1,HS-402F2-A,HS-402F3,HS-402F3-A,HS-402F3-B,HS-405

Classification: Class I (MDR, Annex VIII Rule 13)
UDI-DI 697038425PLTTC

Conforming Assessment Route: Annex IV

We herewith declare that the mentioned above products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer and the notified body. We are exclusively responsible for the Declaration of Conformity.

DIRECTIVES

General applicable regulation: Medical Device Regulation: COUNCIL REGULATION (EU) 2017/745.

Standards applied which compliance can be: list of (harmonized) standard for documented evidence for provided.

Medical device regulation: MDR (EU)2017/745

Standard: ISO 13485:2016; ISO 15223-1:2016; ISO 14971:2019

Signature 

Position RA manager

Place, Date: NANTONG, 2021.05

江苏鹿得医疗电子股份有限公司
HONSUN (NANTONG) CO., LTD.