



EC DECLARATION OF CONFORMITY

Name and address of the manufacturer: / Harbin Howell Medical Apparatus and Instruments Co., Ltd.
NO.134-1, Junmin Street Xiangfang District Harbin, 150046, China;
1/F, No.3 building, Southwest of Hanan 12th street, Nangang Industrial Park, Harbin, 150089, China.

Registered trade name or mark:/
EC Authorized Representative:/ Caretechion GmbH
Niederrheinstr. 71
40474 Düsseldorf, Germany

We declare under our sole responsibility that

Name of the medical device: / Shadowless Operating Lamp:
HE-L500, HE-L600, HE-L700, HE-L700/500, HE-L500/500, HE-L600/600, HE-L700/700, HE-L5+5, HE-L5+3, HE-L5, HE-L3, HE-K9/4, HE-K4, HE-K9, HE-L4, HE-K5

Product code:/ UMDNS code: 12282

Intended purpose: / It is used for the lighting of the operating room to minimize the shadow of the working area caused by the partial occlusion of the surgeon.

Basic UDI-DI:/ 697444542HE700/500JK

of class: / Rule1, Class I
According to annex VIII of Regulation (EU) 2017/745 /,

Conformity assessment procedure:/ Annex IX (Chapter I+III) of Regulation (EU) 2017/745 /

Notified Body: /
NB Identification number:/ CE

CS reference: / None

Meets the provisions of the Regulation (EU) 2017/745 which apply to it. The declaration is valid in connection with the "final inspection report" of the device. /

2021-07-25, Harbin

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

Name und Funktion / Name and function /
Nom et fonction / Nome e funzione

