

## Enclosure of EC-Certificate

(Production quality assurance system)

according to annex V, Medical Devices Directive 93/42/EEC

**Certificate No.: CQ043563-V**

Manufacturer

**Hydrosun Medizintechnik GmbH**

**Mauchener Str.14**

**D-79379 Müllheim, Germany**

Medical devices concerned:

Name of product	Itemspec.	UMDNS	class
hydrosun <sup>®</sup> Irradiator VIS + wIRA <sup>®</sup> therapy, hyperthermia and light therapy device in the versions: T, FS; FP; PP, FM,FD, WS, DS, WD, DD, WH	500	17-570	Ila
hydrosun <sup>®</sup> /PhotoDyn Irradiator VIS + wIRA <sup>®</sup> therapy hyperthermia and light therapy device in the versions: T, FS; FP; PP, FM,FD, WS, DS, WD, DD, WH	501	17-570	Ila
hydrosun <sup>®</sup> PhotoDyn <sup>®</sup> Irradiator VIS + wIRA <sup>®</sup> therapy, hyperthermia and light therapy device in the versions: T, FS; FP; PP, FM,FD, WS, DS, WD, DD, WH	505	17-570	Ila
hydrosun <sup>®</sup> Irradiator VIS + wIRA <sup>®</sup> therapy, hyperthermia device in the versions: T, FS; FP; PP, FM,FD, WS, DS, WD, DD, WH	300N	17-570	Ila
hydrosun <sup>®</sup> Irradiator VIS + wIRA <sup>®</sup> therapy, heating device in the versions: T, FS; FP; PP, FM,FD, WS, DS, WD, DD, WH	305N	17-570	Ila
hydrosun <sup>®</sup> -system wIRA <sup>®</sup> therapy, hyperthermia device	6000L	17-570	Ila
hydrosun <sup>®</sup> -Irradiator, wIRA <sup>®</sup> -Irradiator, PhotoDyn <sup>®</sup> -Irradiator	750	17-570	Ila

This annex replaces the annex of the Certificate No. CQ043563-V from 21 December 2004.

# CE 0535

Accreditation granted by  
Zentralstelle der Länder  
für Sicherheitstechnik

## ZLS

ZLS-ZQ-236/04

Darmstadt, 15 November 2006

  
Certification Body

