

## DECLARATION OF CONFORMITY

Manufacturer: Assing S.p.A.  
Via E. Amaldi, 14  
00015 Monterotondo, Roma, Italy

Product Name	Model	Classification	Rule
Radiological Tilting Table	Helios DRF	II B	Annex II – excluding paragraph 4, of the Directive 93/42/EEC on Medical Device
Radiological Tilting Table	Helios SFD	II B	

We, hereby declare that we will look after the proper application of the quality system earmarked for design, production and final inspection of the medical equipment stipulated below.

We do assure and declare that the aforementioned products meet requirement of Medical Device Directive 93/42/EEC Annex II – excluding paragraph 4, concerning medical equipment and that we have been familiarized ourselves with a result of design documentation evaluation and that we have been authorized to use “CE” mark with identification number: 1370.

Standard Applied: the applicable section of the following standard for safety and quality were applied: ISO 9001:2015; ISO 13458:2016; CE1370.

NOTIFIED BODY: Bureau Veritas Italia S.p.A.  
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CERTIFICATES: ISO 9001:2015 No: IT270542  
ISO 13485:2016 No. IT272156-1  
CE 1370 No. IT272133 - 1

30.11.2020  
MONTEROTONDO / ITALY

Giselda De Silva  
General Manager / Assing S.p.A.

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