

# Declaration of Conformity

The undersigned hereby declares, on behalf of ScandiDos AB (publ), under our sole responsibility that the product referenced below to which this declaration relates, is in conformity with the provisions of:

- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices .

**Manufacturer:** ScandiDos AB

Dag Hammarskjölds väg 52A, third floor SE-752 37, Uppsala,  
Sweden

**Single Registration Number:** SE-MF-000035494

Product Name	Intended Use
Delta4 Phantom+	Quality assurance of patient specific treatment delivery prior to the treatment in IMRT (including VMAT) and 4DRT (e.g., respiratory gating and tumour tracking). Quality assurance of the radiation delivery system.
Delta4 Phantom+ IMRT	
Delta4 Phantom+ MR	
Delta4 Phantom+ Wired	

**Basic UDI-DI:** 73500051800002EG

**Classification:** Class I(m)

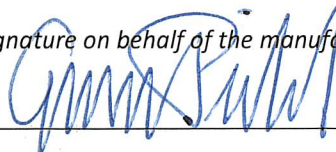
**Conformity Assessment:** Annex IX Chapters I & III

**Notified Body:** Intertek Medical Notified Body AB, Notified Body number: 2862

**Certificate No:** 28620160804

Uppsala, 2024-05-23

Signature on behalf of the manufacturer:



Gustaf Piehl, CEO and President

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