Delta4
by ScandiDos

Doc No: D017 04 135 01

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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