

Subject  
Declaration

Our reference  
RA/QA-23.018

Date  
08 February 2023

To whom it may concern,

Canon Medical Systems Europe B.V., the Authorized Representative in the European Union of Canon Medical Systems Corporation, herewith confirm that the following Canon medical device:

Whole Body Computed Tomography Scanner TSX-305A (Aquilion ONE)

- Is in compliance with the essential requirements of the Medical Device Regulation 2017/745/EU and subsequent amendments. The legacy TSX-305 A (Aquillion ONE) in the market and/or in stock are in compliance with the essential requirements of the Medical Device Directive 93/42/EEC<sup>1</sup> which satisfy Directive 2014/30/EU on the approximation of the laws of the Member States relating to electromagnetic compatibility.
- Comply with EN 60601-1-2:2015 (electromagnetic compatibility for medical electrical equipment) and related standards.

Yours sincerely,

Canon Medical Systems Europe B.V.

D. Azeloğlu  
Director  
Regulatory Affairs & Quality Assurance

<sup>1</sup>Medical Device Directive 93/42/EEC (article 2.7) is a specific Directive with the meaning of Article 2.3 of Directive 2014/30/EU.