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DECLARATION OF CONFORMITY

Manufacturer: InterSystems Italia s.r.l.

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Centro Direzionale Leoni, 5th floor

We, overseeing the development, release, and support of InterSystems TrakCare Solution, declare under our sole responsibility that the following releases of TrakCare Solution:

Device name: *TrakCare Italy*

Device numbers (unique identifier): ITXX

to which this declaration relates, are in conformity with Council Directive 93/42/EEC of 14 June 1993 concerning medical devices as amended by 2007/47/EC per Annex VII of Council Directive 93/42/EEC.

Product Classification: Class I

Signed for and on behalf of: InterSystems Italia Srl on 21 May, 2021