

ITALRAY s.r.l. • 50018 Scandicci (Firenze) Italia • Via del Parlamento Europeo 9d Tel. +39 055 7228511 • Fax +39 055 7228512 C.F./EEC VAT. IT00892270489 • C.C.I.A.A. 248973 Iscriz. Trib. 23170 Firenze • Iscriz. RAEE IT0802000000971 e-mail: info@italray.it • web: www.italray.it

Date: 26/08/2022

To: Procurement Officials

MANUFACTURER'S DECLARATION

Dear Sirs,

We, ITALRAY S.r.l., official manufacturers of Medical Imaging Equipment, having factories at Via del Parlamento Europeo 9D 50018 Scandicci Florence Italy, hereby confirm that we are already in the process of updating all the products of our CE Certificate number 216568-2017-CE-ITA-NA-PS and ISO 13485:2016 Certificate N. 1405.2019, to the new EU Medical Device Regulation MDR 2017/745

Best Regards

Name: Eng. Stefano Porciani

Title: SEEME APAC Export Sales Manager

Manufacturer: ITALRAY S.r.l.

Date: 26/08/2022

In faith

Eng. Stefano Porciani

ITALRAY Export Area Manager

Via del P. Europeo, n. 9/D 50018 SCANDICCI - FIRENZE - ITALY Tel. +39/055 7228511 - Fax; 055 1228512 VAT. N. IT.: 00892270489