DECLARATION OF CONFORMITY OF MEDICAL DEVICES

SINGLE USE, STERILE SYRINGES AND NEEDLES WITH SAFETY MECHANISM

to the essential requirements of Annex I of Directive 93/42/EEC, as prescribed by Annexes V and VII of Directive 93/42/EEC as amended by Directive 2007/47/EC.

RAYS SPA, with administrative headquarters in via Francesco Crispi 26 - 60027 Osimo (AN) Italy, manufacturer of medicai devices named: **"HYPODERMIC AND INSULIN SYRINGES WITH AND WITHOUT NEEDLE, HYPODERMIC NEEDLES AND SCALP VEIN SETS, IV CANNULA, LANCETS, PEN NEEDLES, FISTULA NEEDLES, STERILE FOR SINGLE USE WITH SAFETY MECHANISM",**

DECLARES

under its own responsibility that the devices comply with all the essential requirements required by Legislative Decree 46/97 implementing Directive 93/42/EEC and subsequent amendments and additions.

To this purpose, it guarantees the following:

8. That the devices in question meet the essential requirements of Directive 93/42/EEC and subsequent amendments and additions;
9. That the devices in question are to be considered as belonging to Class IIa according to Annex IX rule 6;
10. To undertake to keep and keep available the Product Technical File, for a period of at least five years from the last date of placing on the market of the last serial number produced at the office of the Technical File Manager;
11. That the devices meet the requirements of the following standards:
    - EC 1-2019 UNI EN ISO 7886-1:2018
    - UNI EN ISO 7864:2016
    - UNI EN ISO 8537:2016
    - UNI EN ISO 11135:2020
    - UNI EN 556-1:2002
    - UNI EN 868-2:2017
    - UNI EN ISO 11607-1:2020
    - EC 1-2017 UNI CEI EN ISO 15223-1:2017
    - UNI EN ISO 10555-5:2013
    - UNI CEI EN 1041:2013
    - UNI CEI EN ISO 14971:2020
    - Directive 2010/32/UE

12. That the devices in question are manufactured and marketed as indicated in the Product Technical File as part of the application of a company Quality System;
13. That the Quality System of RAYS SpA for **"HYPODERMIC AND INSULIN SYRINGES WITH AND WITHOUT NEEDLE, HYPODERMIC NEEDLES AND SCALP VEIN SETS, IV CANNULA, LANCETS, PEN NEEDLES, FISTULA NEEDLES, STERILE FOR SINGLE USE",** has been certified by the Notified Body n. 1370 BUREAU VERITAS SpA, Viale Monza 347 - 20126 Milan with Certificate IT268973 expiring 13/12/2022.
14. That all the documentation concerning the devices in question is kept by the Quality Manager of RAYS S.p.A, at the headquarters in Via Francesco Crispi 26, 60027 Osimo.

Osimo, 16/02/2021

RAYS SPA
The Chairman
Stefano Marconi