

FRENCH REPUBLIC

Ministry of Labour, Health, Solidarity
and Family

Order of

relating to the refurbishing of goods pursuant to Article L. 5212-1-1 of the Public Health Code

NOR:

The Minister for Labour, Health, Solidarity and Family and the Minister for the Economy, Finance and Industrial and Digital Sovereignty,

Having regard to Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (codification);

Having regard to the Public Health Code, in particular Articles L. 5212-1-1 and R. 5212-44 thereof;

Having regard to the Social Security Code, in particular Articles L. 165-1 and L. 165-1-8 thereof;

Having regard to Decree No 2021-1473 of 10 November 2021 amending Decree No 2009-697 of 16 June 2009 on standardisation, in particular Article 17 thereof;

Having regard to notification No 2023/XXX/FR sent on .././..... to the European Commission;

Hereby order:

Article 1

In accordance with Articles L. 5212-1-1 and R. 5212-44 of the Public Health Code, refurbishment operations carried out by the certified centres or professionals mentioned in Article R. 5212-46 of the Public Health Code must comply with French standard NF S97-414, '*Activité de remise en bon état d'usage de dispositifs médicaux à usage individuel - Exigences générales et de sécurité*' (Refurbishment of medical devices for individual use – General and safety requirements) mentioned in the annex to this Order.

Article 2

The specifications of the standard referred to in the annex to this Order relating to refurbishment, or any standards legally recognised in another Member State of the European Union, in Turkey or in a State party to the Agreement on the European Economic Area and

guaranteeing an equivalent level of safety and quality, shall be binding on the certified centres or professionals referred to in Article R. 5212-46 of the Public Health Code, in order to ensure the quality and safety of use of the refurbished device.

Article 2

This Order shall be published in the *Official Journal* of the French Republic.

Done on

The Minister for Labour, Health, Solidarity and Family,
For and on behalf of the Minister:

The Minister for the Economy, Finance and
Industrial and Digital Sovereignty,
For and on behalf of the Minister:

ANNEX

STANDARD TO BE ENFORCED FOR CERTIFICATED CENTRES OR PROFESSIONALS REFURBISHING MEDICAL DEVICES

1) Enforceable standard

NF S 97-414: Refurbishment of medical devices for individual use – General and safety requirements

2) Implementation details

For the purposes of applying Article L. 5212-1-1, the refurbishment of a medical device corresponds to all servicing and maintenance work carried out on a device already put into service within the meaning of point 6 of Article R. 5211-4, with a view to enabling it to be redistributed to other patients in accordance with the procedures laid down by the manufacturer in the instructions for use. Such work shall be carried out only by the certified centres or professionals mentioned in Article R. 5212-46.

Standard NF S 97-414 applies to all servicing and maintenance work carried out on single-use medical devices included in the list referred to in Article L. 5212-1-1 of the Public Health Code.