

**ANNEX 5 - Field Safety Notice**

**Urgent Field Safety Notice**

**Commercial name of the affected product: RF AMICA PROBE**

**FSCA-identifier: Our internal Ref. 13/17**

**Type of action products recall.**

Date: 20.02.2017

Attention: Vigilance Competent Authority

**Details on affected devices:**

Disposable radiofrequency applicator for interstitial or intraoperative use for microwave thermoablation of biological tissues.

RFH17200E20V1 HS lot 27617

RFH17150E35V1 HS lot 27616

[www.hshospital!service.com](http://www.hshospital!service.com)

**Description of the problem:**

A possible error in packaging can be present on code RFH17200E20VI lot number 27617 and RFH17150E35V1 HS lot 27616

**Advise on action to be taken by the user:**

Please check if RFH label and inner RF label report same code and lot number. Correct label is the one inside the inner packaging (RF label is the correct one).

In case two labels show different information please send us back the product and it will be promptly replaced.

**Contact reference person:**

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**HS Hospital! Service SpA**

Sede legale/Registered Office: Via Zosimo . 13 - 00178 Roma, ITALY

Stabilimentodi produzione/Factoy. Via Angela Vacchi, 23/25- 04011 Aprilia (Latina), ITALY

P.IVA 01296201005 - CF04742650585 - Capitale Sociale €500.000000 Inte.Ves.- REA di Roma n° I 153156

Phone +39 06 9201961 - Fax+39 0692727871 - Fax Orders+ 399275519 - [www.hshospitalservice.com](http://www.hshospitalservice.com).

