

The module will be used with the host device (model PS1098) and as such, required testing and approval is completed. Use with any other host device may or may not require additional testing and approval. Consult Hardware Compliance Engineering for assistance.

The RFID module (Model: SRFAX01) includes the sterile adapter mount (P/N 318325), the distal PSM nose (P/N 318331), and the SRFA PCA (P/N 352350).

The module will be labeled to identify FCC ID (2AAZF-SRFAX01), IC ID (11508A-SRFAX01), and Model (SRFAX01). The label is P/N 510176-01, having white background with black text, and must be attached in a manner such that it will remain fastened to the device during the expected life of the product. The “minimum size and font” is that the text must be legible. Label will be applied on the sterile adapter mount near the SRFA location. It will not be visible when installed on host location. This is acceptable because the approval ID information will be marked on the rear vent panel of the host device.

The intentional radiator symbol will be included with the approval ID information (refer to 880175-02) on the host device, as required per EN60601-1-2. This marking will be readily visible to the user of the host device without the use of tools.

Note: Statements below that are within quotation marks have fixed wording.

FCC

The host product must be labeled with the following:

“Contains FCC ID: 2AAZF-SRFAX01”

The host product manual must include following statements:

“This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.”

Changes or modifications, not expressly approved by Intuitive Surgical, may void the user’s authority to operate the equipment. (Note: the wording for this statement is not fixed)

Industry Canada

The host product must be labeled with the following (in English and French):

“Contains IC: 11508A-SRFAX01”

The host product manual must include following statements (in English and French):

“Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (eirp) is not more than necessary for successful communication.”

“This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.”

"Conformément à la réglementation d'Industrie Canada, cet émetteur radio peut fonctionner uniquement à l'aide d'une antenne de type et de gain maximum (ou moindre) approuvés pour l'émetteur par Industrie Canada. Pour réduire le risque d'interférence aux autres utilisateurs, le type d'antenne et son gain doivent être choisis afin que la puissance isotrope rayonnée équivalente (PIRE) n'excède pas celle nécessaire à une communication réussie ".

"Cet appareil est conforme au(x) standard(s) des CNR d'Industrie Canada pour appareils radio exempt(s) de licence . Son fonctionnement est soumis aux deux conditions suivantes: (1) ce dispositif ne doit pas causer d'interférences nuisibles, et (2) cet appareil doit accepter toute interférence reçue, y compris les interférences qui peuvent provoquer un fonctionnement indésirable ".