Certificate of Compliance

No. 3X200430.AQD07

Technical Construction File no. 18A092601E-E

Certificate's **AVITA Corporation**

9F, No.78, Sec.1, Kwang-Fu Road, San-Chung District, New Holder:

Taipei City 24158, Taiwan

Certification **ECM Mark:**



Nasal Aspirator Product:

Model(s): NS1, NS12, NS14, NS15, NS16, NS17, NS18, NS21, NS

Series

Verification to: Standard:

> EN 60601-1-2:2015, EN 61000-3-2:2014, EN 61000-3-3:2013, EN 61000-4-2:2009, EN 61000-4-3:2006+A1:2008+A2:2010.

EN 61000-4-4:2012, EN 61000-4-5:2014+A1:2017,

EN 61000-4-6:2013+COR1:2015,

EN 61000-4-8:2010, EN 61000-4-11:2004+A1:2017

related to CE Directive(s):

2014/30/EU (Electromagnetic Compatibility)

Remark: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the technical documentation received from the manufacturer is satisfactory for the requirements of the ECM Certification Mark. The conformity mark above can be affixed on the products accordingly to the ECM regulation about its release and its use.

Additional information and clarification about the Marking:



The manufacturer is responsible for the CE Marking process, and if necessary, must refer to a Notified Body. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecerma.it

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> Reviewer Technical expert Amanda Payne

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Approver ECM Service Director