



DECLARATION OF CONFORMITY TO DIRECTIVE 93/42 / EEC

The manufacturer Ibramed Industria Brasileira de Equipamentos Medicos LTDA
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Brasilia_

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We, the Manufacturer Company, hereby declare that Products:

- 1.SONOPULSE 1.0 and 3.0 MHZ
2. SONOPULSE Compact 1 MHZ
3. SONOPULSE Compact 3 MHZ

Clasa de risco - II - MEDIO RISCO

Complies with Directive 93/42 / EEC, in accordance with Annex IX of Directive 93/42 /
EEC (medical device hazard class: I).

The conformity of the specified product is confirmed by certification of the
quality management system of the Company - the Manufacturer for compliance with
the requirements of CE, ISO 9001: 2015, ISO 13485: 2016 by a notified body

Date signature

02/01/2023

Daniel Blanco Marques
Commercial Manager



RAZÃO SOCIAL: IBRAMED - Indústria Brasileira de Equipamentos Médicos LTDA
SEDE: Av. Carlos Burgos, nº 2800 - Jardim Itália - CEP: 13.901-080 - Amparo/SP
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