

## STATEMENT

### TRANSITION FROM THE MDD 93/42/EEC DIRECTIVE TO THE EU REGULATION MDR 2017/745 ON MEDICAL DEVICES

#### PREMISE

The new European Regulation 745/2017 (MDR) officially became effective on 26 May 2021, replacing the Directive 93/42 / EEC (MDD) on Medical Devices.

It is a very important regulatory change that affects all those involved in the sector, from the manufacturer to the distributor of a device, dictating new requirements and responsibilities for all operators involved in the distribution chain of Medical Devices.

The concept of co-responsibility between the different economic operators and the concept of traceability of Medical Devices become the key elements of this Regulation.

Not only the manufacturer but also the downstream distributors become responsible for an active communication of reports from the market / customers on potential Medical Device complaints and other documentary charges within the scope of the certifications in force.

#### Behringer Srl DECLARES

that it will continue to place on the market its Medical Devices in compliance with the applicable requirements of Directive 93/42 / EEC and subsequent amendments and additions, Annex II excluding point 4, implemented in Italy with Legislative Decr. 46 of 1997/02/24 and subsequent amendments and additions until **2023/07/09**, the expiry date of the **MED 9850 certificate (revision in force n ° 45 of 19/05/2021)** in accordance with the *Transitional Provisions* indicated in the Article 120 of the new MDR which states that " *Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC from 25 May 2017 shall remain valid until the end of the period indicated on the certificate, which shall not exceed five years from its issuance. They shall however become void at the latest on 27 May 2024*".

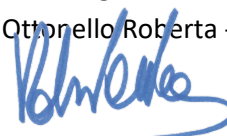
Until that day the medical devices will be placed on the market accompanied by an **EC Declaration of Conformity** in accordance with the requirements of Directive 93/42/EEC and subsequent amendments and additions.

Behringer remains at the complete disposal of its Customers and Distributors for any clarification or support regarding the requirements and responsibilities dictated by the new MDR.

Genoa, June 17, 2021

Behringer S.r.l.

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