Portugal



EU DECLARATION OF CONFORMITY

For medical devices

according to Regulation (EU) 2017/745



Auto Ribeiro Lda., with main facilities at Rua S. Caetano, 459 and 519 – 4411-701 Canelas, Vila Nova de Gaia, Portugal, declares under its own responsibility that the following product according to REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 and with the following mentioned standards.

Auto Ribeiro Lda. maintains a Quality Management System that fulfills the requirements of NP EN ISO 9001. Copies of Auto Ribeiro, Lda. ISO 9001 certificate issued by SGS are available upon request.

Product: Estrado

Manufacturer: Auto Ribeiro Lda.

Model: E400LS

Risk Class of the Device: Class I

Device ID: 434865

Basic UDI-DI: 5600786656FASTNERSS

CDM: 74068520

Based on Standards:

EN 1865-5

Patient handling equipment used in road ambulance.

-Stretcher Support

EN 1789

Medical vehicles and their equipment - Road Ambulances

DIRECTIVA 2006/42/CE

Machinery

ECE Regulation 10R05

Electromagnetic compatibility (EMC)

EN ISO 9001

System of quality management

Place and date:

Canelas - Vila Nova de Gaia, 05-12-2022

Signature

Ribeiro Lda

Auto

VIF 38(143498)

Name:

Alexandre Miguel de Oliveira Vila Pouca (Technical Director)









