

DEVICE DESCRIPTION AND SPECIFICATION

1.6 Declaration of Conformity

Legal manufacturers name	Archy Medical B.V.
Manufacturer address	Westhove 119 1187 DB Amstelveen The Netherlands
Single Registration Number (SRN)	NL-MF-000002620
Basic UDI-DI	87202994809LSPXXEGFR
Trade name	Limisan Pro
Classification	Class I
Notified Body name	n.a.
Conformity assessment procedure	MDR 2017/745 Annex II and III

This declaration of conformity is issued under the sole responsibility of Archy Medical B.V. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System of the legal manufacturer.

A complete overview of all devices related to this Declaration of Conformity is included in the Annex to this document and is valid for all products concerned bearing the CE marking. All supporting documentation is retained at the premises of the legal manufacturer.

Signature:

Rutger Jongerius
Managing Director

Place and date of issue:

Amstelveen, 15-06-2021