

MANUFACTURER'S DECLARATION OF CONFORMITY

SYSTEM

This is a declaration of conformity made under Article 12 of the European Medical Device Directive 93/42/EEC

Manufacturer's name: Inovytec Medical Solutions Ltd.
Business address: 3 Hanagar St., Hod Hasharon, 4501306, Israel
System: SALI D System: SALI-10000 contains the following:

- One set of AED Pads: SALI-01010
- One SpO2 Finger Probe: SALI-01080

Classification: Class of the system – Class IIb

Scope of application: The scope of this application applies to all SALI D devices.

The manufacturer has evidence that the relevant conformity assessment procedures have been applied to each medical device in the package and that each medical device in the package complies with the applicable provisions of the essential principles.

Each medical device in the package is intended to be used for its original intended purpose, and is intended to be used in accordance with the approved indications for use specified by the manufacturer of those items.


The mutual compatibility of each medical device, and any other goods, in the package has been verified in accordance with any instructions for use provided by the manufacturer of each item or the approved indications for use of each item; and that the manufacturer has manufactured the system or procedure pack in accordance with those instructions (if any) or indications.

The information supplied with the system or procedure pack for the use of the system or procedure pack includes instructions for use provided by the manufacturer for each item in the package.

The process of manufacturing the system or procedure pack, and the verification and packaging of the system or procedure pack, has been subjected to a documented method of internal control and inspection that ensures the safety, quality, performance and effectiveness of each item in the package.

Issue date: May 21, 2018

Expiry date: June 11, 2022


Signature _____
Inovytec Medical Solutions Ltd
514576503 .D.I

Rony Gaygo, RA & QA Manager