

## **MEDICAL DEVICES MANUFACTURED BY SCW Medicath Ltd**

STATEMENT FOR CONTINUED COMPLIANCE OF THE MEDICAL DEVICES MANUFACTURED BY  
SCW Medicath Ltd WITH THE REQUIREMENTS OF THE DIRECTIVE 93/42/EEC OF THE  
EUROPEAN

PARLIAMENT AND COUNCIL.

REVISION 01 – 06/03/2024

SCW Medicath Ltd

Tel : +86-755-89926266 ext 4 – Fax : +86-755-89668199 ext 827

NO.4 Baolong 6th Road, Baolong industrial Town, Longgang District, Shenzhen, P.R. China

[www.scwmed.com](http://www.scwmed.com)

To Whom It May Concern

We, SCW Medicath Ltd , located NO.4 Baolong 6th Road, Baolong industrial Town, Longgang District, Shenzhen, P.R. China,

DECLARES

- *There is no significant change in the design and intended use of the Medical Devices manufactured by SCW Medicath Ltd;*
- *Having put in place and running a sustainable and sound quality management system(QMS) within the purview and perseverance of MDR Article 10(9);*
- *An agreement has been signed between SCW Medicath Ltd with TÜV SÜD and TUV Rheinland (Notified Body), for assessment of conformity of medical devices manufactured by SCW Medicath Ltd in accordance with Article 4.3, Annex VII of the MDR;*

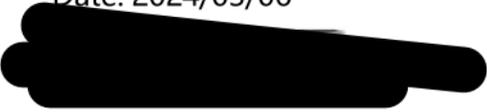
Consequently, according to the Regulation 2023-607, our EC Certificate No. G1 104068 0002 and No. HD 60144232 0001 are still valid despite the expiry date.

Please note that all persons having the right of access to this information are committed to respect the properties of SCW Medicath Ltd, and must not communicate to a third party, nor reproduce the documents without prior authorization.

Steve Wang

General Manager

Date: 2024/03/06



SCW Medicath Ltd

Tel : +86-755-89926266 ext 4 – Fax : +86-755-89668199 ext 827

NO.4 Baolong 6th Road, Baolong industrial Town, Longgang District, Shenzhen, P.R. China

[www.scwmed.com](http://www.scwmed.com)