Ministry of Health, Welfare and Sport
CIBG
P.O. Box 16114
2500 BC The Hague
THE NETHERLANDS

STATEMENT

The undersigned herewith declares that according to the Decree on Medical Devices, which is based on the European Directive 93/42/EEC concerning medical devices,

Bayer Medical Care B.V.
Horsterweg 24
6199 AC Maastricht-Airport
THE NETHERLANDS

acts as authorised representative of the manufacturer.

The manufacturer:

Bayer Medical Care Inc.
1 Bayer Drive
Indianola PA 15051-0780
UNITED STATES OF AMERICA

is authorised to manufacture and/or supply the medical device/devices mentioned below:

See product list

This device/these devices may be placed on the Dutch market and on the markets of the other Member States of the European Union, and be exported to States and territories outside the European Union. This free sale certificate may only be used for export outside the European Union.

The present statement is drawn up at the request of the interested party in order to be submitted to the Health Authorities of COLOMBIA.

This statement is valid until May 26, 2024.

The Hague, February 2, 2022

On behalf of the Minister for Health, Welfare and Sport
Farmatec | CIBG

Dr. M.J. van de Velde

Mr. M.J. van de Velde
Head of Department

Our reference: 20220215
Certificate number: 34854