To Whom it May Concern

10. Feb 2022

Manufacturer Statement

Roche Diabetes Care packaging configuration under new legislations MDR/IVDR

We,

Roche Diabetes Care GmbH
Sandhofer Strasse 116
68305 Mannheim
Germany,

confirm that all our product configurations containing more than one component being a product in itself are considered a procedure pack according to Article 22 of Regulation (EU) 2017/745, also referred to as "MDR". This is valid for both our packaging configurations that include medical devices as well as our Blood glucose monitoring *Kits* and *Sets* that contain both medical devices and in-vitro diagnostic medical devices according to their designated regulation.

This implies the following for all our packaging configurations (meaning: Blood glucose monitoring Kits and Sets, Insulin Delivery System Sets and Lancing kits):

- A EU Declaration of Conformity for each of the included products including the respectively assigned risk class is issued and signed.
- A Manufacturer Declarations according to Article 22 (2017/745) for the packaging configurations is issued and signed.
- The outer package of these packaging configurations does not bear an additional CE mark, but depict the CE marks of the individual included products.
- Basic-UDI-DI Codes are assigned to each packaging configuration.
- Free Sales Certificates (Certificates of Marketability) for the above mentioned packaging configurations can be issued referring to Regulation (EU) 2017/745.

Roche Diabetes Care GmbH
Sandhofer Strasse 116
68305 Mannheim

Sincerely,
Roche Diabetes Care GmbH
i.V./on behalf of the company

Dr. Alexander Rügner
Head of Regulatory Affairs Mannheim OUS submission and IDS

i.V./on behalf of the company

Christian Bohrt
Senior Manager Regulatory Affairs