

To whom it may concern

Manufacturer Declaration - Safety in flight –

Löwenstein Medical Technology GmbH + Co. KG Kronsaalsweg 40 • 22525 Hamburg • Germany

We hereby confirm that the following sleep-therpay devices are therapeutic medical equipment:

prisma20C (WM100TD)
prisma20A (WM100TD)
prismaCR (WM100TD)
prisma25S (WM100TD)
prisma25S-C (WM100TD)
prisma25ST (WM100TD)
prisma30ST (WM100TD)
prismaLAB (WM100TD)
prisma SMART (WM090TD)
prisma SOFT (WM090TD)
prisma SOFT plus (WM090TD)
prisma SOFT plus (WM090TD)
prisma SOFT max (WM090TD)
prisma SOFT max (WM090TD)
prisma SOFT max (WM090TD)
prisma SOFT max (WM090TD)

The devices are suitable for transport and use in aircrafts and comply with the requirements in accordance with RTCA/DO-160G Section 21, Category M.

Owe Rambau Regulatory Affairs Manager Löwenstein Medical Technology GmbH + Co. KG

