

An alle, die es betrifft

Bestätigung der Herstellerfirma - Sicherheit im Flugzeug -

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

Hiermit bestätigen wir, dass es sich bei den folgenden Schlaftherapiegeräten um
therapeutische Medizinprodukte handelt:

- prisma20C (WM100TD)**
 - prisma20A (WM100TD)**
 - prismaCR (WM100TD)**
 - prisma25S (WM100TD)**
 - prisma25S-C (WM100TD)**
 - prisma25ST (WM100TD)**
 - prisma30ST (WM100TD)**
 - prismaLAB (WM100TD)**
 - prisma SMART (WM090TD)**
 - prisma SOFT (WM090TD)**
 - prisma SMART plus (WM090TD)**
 - prisma SOFT plus (WM090TD)**
 - prisma SMART max (WM090TD)**
 - prisma SOFT max (WM090TD)**
 - prismaAQUA (WM100TH)**

Die Geräte sind für den Transport und die Verwendung in Flugzeugen geeignet und erfüllen die Anforderungen gemäß **RTCA/DO-160G Section 21, Category M**.

Julia
Lewalter
Digital
unterscriben
von Julia Lewalter
Datum: 2024.08.06
07:06:00 +02'00'

Julia Lewalter
Regulatory Affairs Manager
Löwenstein Medical Technology GmbH + Co. KG

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 SMART plus (WM090TD)
prisma SOFT plus (WM090TD)
prisma SMART max (WM090TD)
prisma SOFT max (WM090TD)
prismaAQUA (WM100TH)

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** and are considered FAA compliant.

 Digitally signed by
Christoph Lemke
Date: 2023.03.09
12:28:19 +01'00'

Dr. Christoph Lemke
CQO, Director Quality and Regulatory Affairs
Löwenstein Medical Technology GmbH + Co. KG