

Declaration of Conformity

We declare that the 429000 Control Omni including

| | |
|-------------|--|
| 429010 | Control Omni Docking station |
| 429020 | Control Omni Charger GEW100 |
| 429035 | Control Omni Headset |
| 429030 | Control Omni Micro SD Card incl. USB adapter |
| 429025 | Control Omni Stylus |
| 429045 | Control Omni Rubber protection |
| 890410 | Control Omni Necklace |
| 809210 | Control Omni User guide SE/GB |
| 809220 | Control Omni Manual settings SE |
| 809220 | Control Omni Manual settings GB |
| 100331-1616 | Control Omni Manual Dockingstation SE/GB |

conforms to the Medical Device Directive 93/42/EEC, Class 1 products,

SFS 1993:584 and LVFS 2003:11.

Referring standards:

Medical electrical equipment EN 60601-1, Edition 3.

SS-EN ISO 14971 Medical devices-Application of risk management to medical devices.

Date

June 17, 2011



Erland Pontusson

CEO