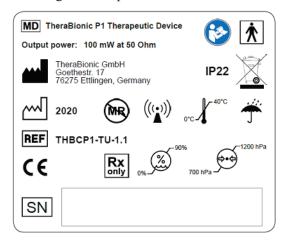
9 LABELING

Draft Instruction for Use for the TheraBionic P1 HDE device is provided as Appendix 9-1.

Component Labels

Labeling of Therapeutic Device



Product labeling Therapeutic Device



The rating plate is glued on the back of the device housing of the Therapeutic Device. The bar code label is glued into the empty SN field on the label.

Labeling of Patient Spoon



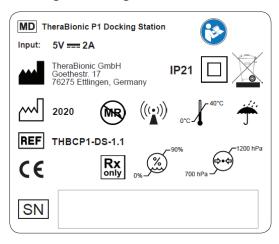




Patient Spoon labeling

Method: laser engraving, Size: L 7 mm x W 7 mm Data-Matrix code and serial number.

Labeling of Docking Station



Product label Docking Station



The rating plate is glued on the back of the device housing of the Docking Station. The barcode 128 with the HW-ID (individual hardware identification of the circuit board) is affixed by the manufacturer (EKM) on the rating plate in the field next to the symbol for the serial number on the rear of the device housing. The algorithms and the above representation of the SN are described in the Labelling specification.