Claims

1. A medical system ~~(144)~~ comprising:
   i) a housing ~~(146)~~;
   ii) a preassembled functional module ~~(110)~~ received in the housing ~~(146)~~, the preassembled functional module ~~(110)~~ comprising
      a. an analyte sensor ~~(112)~~ for detecting at least one analyte in a body fluid of a user;
      b. an electronics unit ~~(120)~~ electrically connected to the analyte sensor ~~(112)~~; and
      c. an insertion component ~~(114)~~ for inserting the analyte sensor ~~(112)~~ into a body tissue of the user; and
   iii) at least one removable protective cap ~~(148)~~ connected to the housing ~~(146)~~, covering the preassembled functional module ~~(110)~~,
   wherein the preassembled functional module ~~(110)~~ further comprises at least one sterility cap ~~(116)~~, which at least partially surrounds the insertion component ~~(114)~~, wherein the at least one sterility cap ~~(116)~~ is at least partially surrounded by the protective cap ~~(148)~~, wherein the sterility cap ~~(116)~~ comprises at least one sterility testing access ~~(140)~~, the sterility testing access ~~(140)~~ comprising at least one of a septum ~~(142)~~ and a multiple-step sealing ~~(162)~~.

2. The medical system ~~(144)~~ according to claim 1, wherein the multiple-step sealing ~~(162)~~ comprises a plurality of circumferential sealing elements ~~(164)~~ having differing equivalent diameters, the circumferential sealing elements ~~(164)~~ being disposed within an interior space ~~(118)~~ of the sterility cap ~~(116)~~.

3. The medical system ~~(144)~~ according to any one of claims 1 or 2, wherein the sterility cap ~~(116)~~ comprises a tubular sidewall ~~(166)~~ surrounding a sterility testing access opening ~~(168)~~, wherein the sterility testing access opening ~~(168)~~ is closed by at least one of the septum ~~(142)~~ and a removable stopper ~~(170)~~.

4. The medical system ~~(144)~~ according to any one of claims 1-3, wherein the sterility cap ~~(116)~~ is accessible from an outer side ~~(152)~~ of the medical system ~~(144)~~, wherein an access to the sterility cap ~~(116)~~ is sealed by a removable seal ~~(152)~~.

5. The medical system ~~(144)~~ according to any one of claims 1-4, wherein the sterility cap ~~(116)~~ is engaged with the removable protective cap ~~(148)~~, such that, when the protective cap ~~(148)~~ is removed from the housing ~~(146)~~, the sterility cap ~~(116)~~ is removed from the preassembled functional module ~~(110)~~.

6. The medical system ~~(144)~~ according to any one of claims 1-5, wherein the sterility cap ~~(116)~~ has at least one side in common with the protective cap ~~(148)~~.

7. The medical system ~~(144)~~ according to any one of claims 1-6, wherein the preassembled functional module ~~(110)~~ further comprises at least one base plate ~~(122)~~, wherein the sterility cap ~~(116)~~ is connected to the base plate ~~(122)~~.

8. The medical system ~~(144)~~ according to any one of claims 1-7, wherein the preassembled functional module ~~(110)~~ further comprises at least one cover element ~~(134)~~, wherein the cover element ~~(134)~~ covers the electronics unit ~~(120)~~ and at least part of the analyte sensor ~~(112)~~.

9. The medical system ~~(144)~~ according to any one of claims 1-8, wherein the sterility cap ~~(116)~~ provides a sealed interior space ~~(118)~~, wherein the analyte sensor ~~(112)~~ and the insertion component ~~(114)~~ at least partially are located within the sealed interior space ~~(118)~~.

10. The medical system ~~(144)~~ according to any one of claims 1-9, wherein the medical system ~~(144)~~ further comprises at least one driving actuator ~~(160)~~ for driving the insertion component ~~(114)~~ into the body tissue of the user.

11. The medical system ~~(144)~~ according to any one of claims 1-10, wherein the preassembled functional module ~~(110)~~ further comprises at least one electrical energy storage device.

12. A method of sterility testing of a medical system ~~(144)~~, the medical system ~~(144)~~ comprising a preassembled functional module ~~(110)~~, the preassembled functional module ~~(110)~~ comprising an analyte sensor ~~(112)~~ for detecting at least one analyte in a body fluid of a user, and an electronics unit ~~(120)~~ electrically connected to the analyte sensor ~~(112)~~ and an insertion component ~~(114)~~ for inserting the analyte sensor ~~(112)~~ into a body tissue of the user, wherein the preassembled functional module ~~(110)~~ further comprises at least one sterility cap ~~(116)~~ at least partially surrounding

the insertion component ~~(114)~~ and optionally at least a part of the analyte sensor ~~(112)~~, wherein the method comprises:

A) inserting a rinsing liquid into an interior space ~~(118)~~ of the sterility cap ~~(116)~~; and

B) microbial testing of the rinsing liquid.

13. The method according to claim 12, wherein the sterility cap ~~(116)~~ has at least one sterility testing access ~~(140)~~, wherein step A) comprises attaching at least one fluidic adapter ~~(172)~~ to the sterility testing access ~~(140)~~, wherein the sterility testing access ~~(140)~~ comprises at least one multiple-step sealing ~~(162)~~, wherein step A) comprises removing at least one stopper from the sterility testing access ~~(140)~~, the stopper being in contact with a first-step sealing ~~(176)~~ of the multiple-step sealing ~~(162)~~, step A) further comprising attaching the fluidic adapter ~~(172)~~ to the sterility testing access ~~(140)~~, wherein the fluidic adapter ~~(172)~~ is in contact with a second-step sealing ~~(178)~~ of the multiple-step sealing ~~(162)~~, wherein the first-step sealing ~~(176)~~ has a larger equivalent diameter than the second-step sealing ~~(178)~~.

14. A method of providing the medical system ~~(144)~~ according to any one of claims 1-11, the method comprising:

I. assembling a part ~~(195)~~ of the preassembled functional module ~~(110)~~, the part ~~(195)~~ of the preassembled functional module ~~(110)~~ comprising the analyte sensor ~~(112)~~ and the insertion component ~~(114)~~ as well as the sterility cap ~~(116)~~ at least partially surrounding the insertion component ~~(114)~~;

II. sterilizing the part ~~(195)~~ of the preassembled functional module ~~(110)~~;

III. assembling the preassembled functional module ~~(110)~~, the assembling comprising electrically connecting the electronics unit ~~(120)~~ to the analyte sensor ~~(112)~~; and

IV. assembling the medical system ~~(144)~~, the assembling comprising receiving the preassembled functional module ~~(110)~~ in the housing ~~(146)~~ and connecting the removable protective cap ~~(148)~~ to the housing ~~(146)~~.

15. The method according to claim 14, the method further comprising:

V. storing the medical system ~~(144)~~.

16. The method according to any one of claims 14-15, the method further comprising:

VI. sterility testing of the medical system ~~(144)~~ by using the method of sterility testing of a medical system ~~(144)~~ according to any one of claims 12-13.