CLAIMS:

1. An irradiation device for insertion into an orifice of the body to provide photodynamic therapy, the device comprising: a housing moulded from a resilient material and adapted to be fully inserted and secured in the orifice, the housing enclosing an LED lamp system and a power source for powering the LED lamp system; wherein the device is independently operational while located in the orifice;

characterised in that: the housing comprises a first housing part for holding the power source and a second housing part for holding the LED lamp system, the first and second housing parts being separable and preferably being formed separately from the LED lamp system; and in that the first housing part consists of a chamber for holding the power source and an opening into the chamber is provided through a resilient opening part, wherein the chamber is closed when the first housing part is joined to the second housing part.

2. A device as claimed in claim 1, wherein the resilient opening part allows for an electrical coupling to pass from the power source to the LED lamp system.

3. A device as claimed in claim 1 or 2, wherein the resilient opening part can be deformed to insert and/or remove the power source into or from the first housing part.

4. A device as claimed in claim 1 or 2, comprising a battery cap to provide an opening into the first housing part

5. A device as claimed in claim 1, 2 or 3, wherein the resilient opening part comprises a neck part for holding the power source within the chamber.

6. A device as claimed in claim 5, wherein the neck part is a resilient narrowing of the entrance to the chamber to a size less than the width of the power source to thereby hold the power source within the chamber.

7. A device as claimed in any preceding claim, wherein the resilient material of the chamber is sized to fit tightly around the power source.

8. A device as claimed in any preceding claim, wherein the power source and LED lamp system are arranged to permit the power source to be electrically connected to the

LED lamp system whilst the first and second parts of the housing are separated from one another.

9. A device as claimed in any preceding claim, wherein the power source is sealed within the housing such that the housing is fluid tight in use.

10. A device as claimed in claim 9, wherein a sealing media is used at the joint between the first and second housing parts.

11. A device as claimed in any preceding claim, wherein the resilient opening part has a coupling part arranged to join to and form a seal with a complementary shaped coupling part on the second housing part.

12. A device as claimed in claim 11, wherein one of the two coupling parts is arranged to be stretched to place it around the other of the two coupling parts, thereby using the elasticity of the resilient material to hold the two housing parts together.

13. A device as claimed in any preceding claim, wherein a part or all of the resilient material is at least partially transparent to light emitted from the LED lamp system, when the device is in use.

14. A device as claimed in any preceding claim, wherein the second housing part to be moulded of a material that is at least partially transparent to light emitted from the LED lamp system when the device is in use, said light exits via a treatment surface on the second housing part and illuminates a treatment area on the patient and wherein the treatment surface has a size and/or shape adapted for complementary fit with said treatment area..

15. A device as claimed in any preceding claim, wherein the second housing part has one or more moulded cavity to fit elements of the LED lamp system.

16. A device as claimed in claim 15, wherein the one or more moulded cavity is enclosed by a fastening lip for securing elements of the LED lamp system within the cavity.

17. A device as claimed in any preceding claim, wherein the device is adapted to be fully inserted and secured in the orifice and does not require connection to an external power supply or light source during operation.

18. A device as claimed in any preceding claim, wherein, in use, the device provides light with a mean irradiance below 50 mW/cm^2.

19. A device as claimed in any preceding claim, wherein the housing comprises a flexible outer portion that can adjust its shape to form a secure fit with the orifice.

20. A device as claimed in any preceding claim, wherein the flexible outer portion forms a continuous surface which tapers outwards towards the rear end of the device.

21. A device as claimed in any preceding claim, further comprising a drug carrying area for carrying a composition comprising a photosensitizer or precursor of a photosensitizer.

22. A device as claimed in claim 21 wherein the drug carrying area is the treatment surface.

23. A device as claimed in claim 21 or 22 wherein the composition comprises a precursor which is 5-ALA, a derivative of 5-ALA or a pharmaceutically acceptable salt thereof, preferably 5-ALA or a precursor of formula (I) and pharmaceutically acceptable salts thereof:

$$R^2{}_2N\text{-}CH_2COCH_2\text{-}CH_2CO\text{-}OR^1 \qquad (I)$$

wherein

R^1 represents a substituted or unsubstituted alkyl group; and

R^2 each independently represents a hydrogen atom or a group R^1.

24. A device as claimed in claim 24 wherein the composition comprises a precursor of formula (I) and pharmaceutically acceptable salts thereof, wherein R^1 is straight chain C_1-C_6 alkyl and both R^2 represent hydrogen.

25. A device as claimed in claim 24 wherein the composition comprises 5-ALA hexyl ester or pharmaceutically acceptable salts thereof.

26. A kit comprising a device as claimed in any of claims 1 to 22 and at least one composition comprising a photosensitiser or precursor of a photosensitiser for use with the device.

27. A kit as claimed in claim 26 wherein the composition comprises 5-ALA or a derivative of 5-ALA or a pharmaceutically acceptable salt thereof, preferably 5-ALA or a precursor of formula (I) and pharmaceutically acceptable salts thereof:

$R^2{}_2N\text{-}CH_2COCH_2\text{-}CH_2CO\text{-}OR^1$ (I)

wherein

R^1 represents a substituted or unsubstituted alkyl group; and

R^2 each independently represents a hydrogen atom or a group R^1.

28. A kit as claimed in claim 27 wherein the composition comprises a precursor of formula (I) and pharmaceutically acceptable salts thereof, wherein R^1 is straight chain C_1-C_6 alkyl and both R^2 represent hydrogen.

29. A kit as claimed in claim 28 wherein the composition comprises 5-ALA hexyl ester or pharmaceutically acceptable salts thereof.

30. A kit as claimed in any preceding claim wherein said composition is provided separately from the device.

31. A kit as claimed in any of claims 26 to 29 wherein said composition is contained in the drug carrying area of the device.

32. A device or kit as claimed in any preceding claim for use in photodynamic therapy, preferably the photodynamic therapy of abnormalities, diseases, lesions or conditions of the female reproductive system, preferably the vagina or the cervix.

33. A device or kit as claimed in claim 32 for use in the photodynamic therapy of HPV infections, intraepithelial neoplasia, dysplasia, precancerous lesions and cancer of the female reproductive system, preferably the vagina and cervix.

34. A method of manufacturing an irradiation device for insertion into an orifice of the body to provide photodynamic therapy, the device comprising: a housing adapted to be fully inserted and secured in the orifice, the housing enclosing an LED lamp system and a power source for powering the LED lamp system; wherein the device is independently

operational while located in the orifice; the method comprising: moulding a first housing part from a resilient material and moulding a second housing part from a resilient material, wherein the first housing part consists of a chamber for holding the power source and an opening into the chamber is provided through a resilient opening part, and the second housing part is for holding the LED lamp system, the first and second housing parts being separate mouldings and preferably being formed separately from the LED lamp system; and the method further comprising: closing the chamber by joining the first housing part to the second housing part in order to form the housing of the device.

35. A method of manufacturing as claimed in claim 34 comprising providing features of the device or kit as claimed in any of claims 1 to 33.

36. A method of photodynamic therapy of a treatment area within an orifice of the body, the method comprising: applying a composition comprising a photosensitiser or precursor to the treatment area and using the device as claimed in any of claims 1 to 25 to provide illumination to treat the treatment area.

37. A method as claimed in claim 36, comprising the photodynamic treatment of abnormalities, diseases, lesions or conditions of the female reproductive system, preferably the vagina and cervix.

38. A method as claimed in claim 36 or 37, comprising the photodynamic treatment of HPV infections, intraepithelial neoplasia, dysplasia, precancerous lesions and cancer of the female reproductive system, preferably the vagina and cervix.

CLAIMS:

1. An irradiation device for insertion into an orifice of the body to provide photodynamic therapy, the device comprising: a housing moulded from a resilient material and adapted to be fully inserted and secured in the orifice, the housing enclosing an LED lamp system and a power source for powering the LED lamp system; wherein the device is independently operational while located in the orifice;

characterised in that: the housing comprises a first housing part for holding the power source and a second housing part for holding the LED lamp system, the first and second housing parts being separable and preferably being formed separately from the LED lamp system; and in that the first housing part consists of a chamber for holding the power source and an opening into the chamber is provided through a resilient opening part, wherein the chamber is closed when the first housing part is joined to the second housing part.

2. A device as claimed in claim 1, wherein the resilient opening part allows for an electrical coupling to pass from the power source to the LED lamp system.

3. A device as claimed in claim 1 or 2, wherein the resilient opening part can be deformed to insert and/or remove the power source into or from the first housing part.

4. A device as claimed in claim 1 or 2, comprising a battery cap to provide an opening into the first housing part

5. A device as claimed in claim 1, 2 or 3, wherein the resilient opening part comprises a neck part for holding the power source within the chamber.

6. A device as claimed in claim 5, wherein the neck part is a resilient narrowing of the entrance to the chamber to a size less than the width of the power source to thereby hold the power source within the chamber.

7. A device as claimed in any preceding claim, wherein the resilient material of the chamber is sized to fit tightly around the power source.

8. A device as claimed in any preceding claim, wherein the power source and LED lamp system are arranged to permit the power source to be electrically connected to the

LED lamp system whilst the first and second parts of the housing are separated from one another.

9. A device as claimed in any preceding claim, wherein the power source is sealed within the housing such that the housing is fluid tight in use.

10. A device as claimed in claim 9, wherein a sealing media is used at the joint between the first and second housing parts.

11. A device as claimed in any preceding claim, wherein the resilient opening part has a coupling part arranged to join to and form a seal with a complementary shaped coupling part on the second housing part.

12. A device as claimed in claim 11, wherein one of the two coupling parts is arranged to be stretched to place it around the other of the two coupling parts, thereby using the elasticity of the resilient material to hold the two housing parts together.

13. A device as claimed in any preceding claim, wherein a part or all of the resilient material is at least partially transparent to light emitted from the LED lamp system, when the device is in use.

14. A device as claimed in any preceding claim, wherein the second housing part is moulded of a material that is at least partially transparent to light emitted from the LED lamp system when the device is in use, said light exits via a treatment surface on the second housing part and illuminates a treatment area on the patient and wherein the treatment surface has a size and/or shape adapted for complementary fit with said treatment area.

15. A device as claimed in any preceding claim, wherein the second housing part has one or more moulded cavity to fit elements of the LED lamp system.

16. A device as claimed in claim 15, wherein the one or more moulded cavity is enclosed by a fastening lip for securing elements of the LED lamp system within the cavity.

17. A device as claimed in any preceding claim, wherein the device is adapted to be fully inserted and secured in the orifice and does not require connection to an external power supply or light source during operation.

18. A device as claimed in any preceding claim, wherein, in use, the device provides light with a mean irradiance below 50 mW/cm^2.

19. A device as claimed in any preceding claim, wherein the housing comprises a flexible outer portion that can adjust its shape to form a secure fit with the orifice

20. A device as claimed in any preceding claim, wherein the flexible outer portion forms a continuous surface which tapers outwards towards the rear end of the device.

21. A device as claimed in any preceding claim, further comprising a drug carrying area for carrying a composition comprising a photosensitizer or precursor of a photosensitizer.

22. A device as claimed in claim 21 wherein the drug carrying area is the treatment surface.

23. A device as claimed in claim 21 or 22 wherein the composition comprises a precursor which is 5-ALA, a derivative of 5-ALA or a pharmaceutically acceptable salt thereof, preferably 5-ALA or a precursor of formula (I) or a pharmaceutically acceptable salt thereof:

$$R^2{}_2N\text{-}CH_2COCH_2\text{-}CH_2CO\text{-}OR^1 \qquad (I)$$

wherein

R^1 represents a substituted or unsubstituted alkyl group; and

R^2 each independently represents a hydrogen atom or a group R^1.

24. A device as claimed in claim 24 wherein the composition comprises a precursor of formula (I) or a pharmaceutically acceptable salts thereof, wherein R^1 is straight chain C_1-C_6 alkyl and both R^2 represent hydrogen.

25. A device as claimed in claim 24 wherein the composition comprises 5-ALA hexyl ester or a pharmaceutically acceptable salt thereof.

26. A kit comprising a device as claimed in any of claims 1 to 22 and at least one composition comprising a photosensitiser or precursor of a photosensitiser for use with the device.

27. A kit as claimed in claim 26 wherein the composition comprises 5-ALA or a derivative of 5-ALA or a pharmaceutically acceptable salt thereof, preferably 5-ALA or a precursor of formula (I) or a pharmaceutically acceptable salt thereof:

$$R^2{}_2N\text{-}CH_2COCH_2\text{-}CH_2CO\text{-}OR^1 \qquad (I)$$

wherein

R^1 represents a substituted or unsubstituted alkyl group; and

R^2 each independently represents a hydrogen atom or a group R^1.

28. A kit as claimed in claim 27 wherein the composition comprises a precursor of formula (I) or a pharmaceutically acceptable salt thereof, wherein R^1 is straight chain C_1-C_6 alkyl and both R^2 represent hydrogen.

29. A kit as claimed in claim 28 wherein the composition comprises 5-ALA hexyl ester or a pharmaceutically acceptable salt thereof.

30. A kit as claimed in any preceding claim wherein said composition is provided separately from the device.

31. A kit as claimed in any of claims 26 to 29 wherein said composition is contained in the drug carrying area of the device.

32. A device or kit as claimed in any preceding claim for use in photodynamic therapy, preferably the photodynamic therapy of abnormalities, diseases, lesions or conditions of the female reproductive system, preferably the vagina or the cervix.

33. A device or kit as claimed in claim 32 for use in the photodynamic therapy of HPV infections, intraepithelial neoplasia, dysplasia, precancerous lesions and cancer of the female reproductive system, preferably the vagina and cervix.

34. A method of manufacturing an irradiation device for insertion into an orifice of the body to provide photodynamic therapy, the device comprising: a housing adapted to be fully inserted and secured in the orifice, the housing enclosing an LED lamp system and a power source for powering the LED lamp system; wherein the device is independently

operational while located in the orifice; the method comprising: moulding a first housing part from a resilient material and moulding a second housing part from a resilient material, wherein the first housing part consists of a chamber for holding the power source and an opening into the chamber is provided through a resilient opening part, and the second housing part is for holding the LED lamp system, the first and second housing parts being separate mouldings and preferably being formed separately from the LED lamp system; and the method further comprising: closing the chamber by joining the first housing part to the second housing part in order to form the housing of the device.

35. A method of manufacturing as claimed in claim 34 comprising providing features of the device or kit as claimed in any of claims 1 to 33.

36. A composition comprising 5-ALA or a derivative of 5-ALA or a pharmaceutically acceptable salt thereof for use in a method for photodynamic therapy of a treatment area on the cervix, the method comprising: administration of the composition to said treatment area, insertion of a device according to any of claims 1 to 25 into the vagina; and illuminating the treatment area with light from the LED lamp system of the device.

37. A composition as claimed in claim 36 comprising a 5-ALA ester or a pharmaceutically acceptable salt thereof, preferably a 5-ALA ester which is a compound of formula (I) or a pharmaceutically acceptable salt thereof:

$R^2{}_2N\text{-}CH_2COH_2\text{-}CH_2CO\text{-}OR^1$

wherein

R^1 represents a substituted or unsubstituted alkyl group; and

R^2 each independently represents a hydrogen atom or a group R^1.

38. A composition as claimed in claim 37, wherein the composition comprises a precursor of formula (I) or a pharmaceutically acceptable salts thereof, wherein R^1 is straight chain C_1-C_6 alkyl and both R^2 represent hydrogen.

39. A composition as claimed in claim 36 comprising 5-ALA hexyl ester or a pharmaceutically acceptable salt thereof.

40. A composition as claimed in any of claims 36 to 39 wherein said composition is a semi-solid or solid composition.

41. A composition as claimed in any of claims 36 to 40 wherein the method for photodynamic therapy is one for cervical cancer and cervical diseases, lesions or conditions, preferably HPV infections, intraepithelial neoplasia, dysplasia and precancerous lesions.

42. A composition as claimed in any of claims 36 to 41, wherein the composition is administered via a drug delivery system provided on the device.

43. A composition as claimed in claim 42, wherein said drug delivery system is a treatment surface which has a size and/or shape adapted for complementary fit with said treatment area.